United States
Environmental Protection Agency

Office of Chemical Safety and
Pollution Prevention

Summary of External Peer Review and Public Comments and Disposition for 1-Bromopropane (*n*-Propyl Bromide)

Response to Support Risk Evaluation for
1-Bromopropane (*n*-Propyl Bromide)

August 2020

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This document summarizes the public and external peer review comments that the EPA's Office of Pollution Prevention and Toxics (OPPT) received for the Draft Risk Evaluation of 1-bromopropane (1-BP). It also provides EPA's response to the comments received from the public and the Science Advisory Committee on Chemicals (SACC) peer review panel.

EPA appreciates the valuable input provided by the public and peer review panel. The input resulted in numerous revisions to the risk evaluation document.

Peer review charge questions[1] are used to categorize the peer review and public comments into specific issues related to the following themes.

1. Systematic Review
2. Occupational Exposure Assessment
3. Consumer Exposure Assessment
4. Environmental Hazard and Risk Characterization
5. Human Health Hazard and Dose-Response Assessment
6. Human Health Risk Characterization
7. General Risk Characterization
8. Content and Organization

For each comment, the original commenter is denoted as either "SACC" (for peer reviewer comments) or by the comment number within the docket (for public comments).

[1] These are the questions that EPA submitted to the panel to guide the peer review process.

List of Comments		
#	**Docket File**	**Submitter**
23	EPA-HQ-OPPT-2019-0235-0023	Jay S. Tourigny, Senior Vice President, MicroCare Corporation
24	EPA-HQ-OPPT-2019-0235-0024	Environmental Protection Network
25	EPA-HQ-OPPT-2019-0235-0025	Suzanne Hartigan, Senior Director, Regulatory and Technical Affairs, American Chemistry Council (ACC)
26	EPA-HQ-OPPT-2019-0235-0026	Adam M. Finkel, Clinical Professor of Environmental Health Sciences, Univ. of Michigan School of Public Health
27	EPA-HQ-OPPT-2019-0235-0027	Ben Gann, Director, Chemical Products & Technology Division, ACC
28	EPA-HQ-OPPT-2019-0235-0028	Honeywell
29	EPA-HQ-OPPT-2019-0235-0029	Albemarle Corporation
30	EPA-HQ-OPPT-2019-0235-0030	Jonathan Kalmuss-Katz, Eve C. Gartner, and Tosh Sagar, Earthjustice
31	EPA-HQ-OPPT-2019-0235-0031	Enviro Tech International, Inc. and ICL Industrial Products
33	EPA-HQ-OPPT-2019-0235-0033	Adam M. Finkel
34	EPA-HQ-OPPT-2019-0235-0034	Environmental Defense Fund
35	EPA-HQ-OPPT-2019-0235-0035	Tracey Woodruff, Professor, Director, Program on Reproductive Health and Environment School of Medicine, University of California
36	EPA-HQ-OPPT-2019-0235-0036	Jon Kalmuss-Katz, Earthjustice
37	EPA-HQ-OPPT-2019-0235-0037	Bob Miller (Albemarle Corporation)
38	EPA-HQ-OPPT-2019-0235-0038	Suzanne Hartigan (American Chemistry Council)
39	EPA-HQ-OPPT-2019-0235-0039	Bob Sussman (Safer Chemicals Healthy Families)
45	EPA-HQ-OPPT-2019-0235-0045	Justin Koscher, President, Polyisocyanurate Insulation Manufacturers Association
46	EPA-HQ-OPPT-2019-0235-0046	Eric Berg, Deputy Chief Research and Standards Division, Occupational Safety and Health (Cal/OSHA), State of California
47	EPA-HQ-OPPT-2019-0235-0047	Robert Stockman, Senior Attorney on behalf of Environmental Defense Fund (EDF)
48	EPA-HQ-OPPT-2019-0235-0048	Massachusetts Toxics Use Reduction Institute (TURI)

List of Comments		
#	**Docket File**	**Submitter**
49	EPA-HQ-OPPT-2019-0235-0049	Liz Hitchcock, Director, Safer Chemicals Healthy Families; Patrick MacRoy, Deputy Director; Environmental Health Strategy Center; Jonathan Kalmuss-Katz, Staff Attorney, Earthjustice; Daniel Rosenberg, Director, Federal Toxics, Natural Resources Defense Council
50	EPA-HQ-OPPT-2019-0235-0050	Suzanne Hartigan, Senior Director, Regulatory and Technical Affairs, American Chemistry Council (ACC)
51	EPA-HQ-OPPT-2019-0235-0051	Ben Gann, Director, Chemical Products & Technology Division, American Chemistry Council
52	EPA-HQ-OPPT-2019-0235-0052	Julia M. Rege, Global Automakers
53	EPA-HQ-OPPT-2019-0235-0053	Swati Rayasam, Program on Reproductive Health and the Environment, Department of Obstetrics, Gynecology and Reproductive Sciences, University of California, San Francisco; for the undersigned academics, scientists, and clinicians
54	EPA-HQ-OPPT-2019-0235-0054	Jonathan Kalmuss-Katz of Earthjustice and Randy Rabinowitz of the OSH Law Project for the United Steelworkers, the UAW, and the AFL-CIO
55	EPA-HQ-OPPT-2019-0235-0055	Enviro Tech International, Inc.
SACC	N/A	Science Advisory Committee on Chemicals (SACC)

Systematic Review		
Charge Question 1.1: Please comment on the approaches and/or methods used to support and inform the gathering, screening, evaluation, and integration of data/information used in the *Draft Risk Evaluation for 1-Bromopropane (1-BP)* **Charge Question 1.2:** Please also comment on the clarity of the information as presented related to systematic review and suggest improvements as warranted.		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 1**	**EPA/OPPT Response**
Need to address inconsistencies in data quality evaluation		
SACC, 25, 31, 35, 47, 50, 53	**SACC COMMENTS:** • Define terms and use them consistently. • Use a consistent citation style throughout the systematic review to make it easier to follow specific references. • Standardize criteria across categories of data as much as possible. • Criteria for different types of information should be more consistent • Update the SR criteria for Methodology/Reliability for Environmental Release and Exposure to reflect current practices or adapt procedures to ensure current criteria are applied consistently. **PUBLIC COMMENTS:** • Data quality evaluation of studies is inconsistent. EPA should describe efforts taken to calibrate the reviews of different reviewers, as some inconsistencies in data quality evaluation both within and across chemicals seem apparent. EPA should also ensure that all studies relied on the draft risk evaluation undergo data quality evaluation. There have been major differences between the three released draft risk evaluations in terms of process and information. • The method used to calculate the overall rating for a particular study is not clearly presented in either the updated criteria document or the risk evaluation and its supporting files. In addition, there are inconsistencies in how EPA handles different sources (see ECHA Criticisms below). • Several problems with EPA's approach to evaluating the epidemiologic evidence were mentioned. EPA provides	EPA appreciates the comments and is currently in the process of updating its Systematic Review protocol. In addition, EPA is seeking feedback from the National Academies of Science (NAS) on its Systematic Review process, including data evaluation criteria and data quality rating methods used in TSCA Risk Evaluations. The NAS webinars are currently scheduled from June through August 2020. EPA will consider all comments and feedback received in updating its Protocol. In response to SACC and public comments, EPA has completed review and data quality evaluation of additional studies relied upon within the Final Risk Evaluation. EPA has also incorporated additional discussion around rationales for including or excluding certain studies within the Final Risk Evaluation. . Additional language was added to Section 1.5 of the Final Risk Evaluation to discuss methodology used as well as some discussion surrounding the revisions to the data quality criteria for epidemiological studies. The three epidemiological studies referenced by the commenter were not excluded from consideration. They were considered qualitatively in the weight of evidence for neurological effects. However, they could not be used for dose-response purposes in this evaluation. This is discussed in response to several other comments and additional language was added to Section 3.2 explaining why the studies could not be used for dose-response purposes. And, the overall rating methodology is discussed in the *Application of Systematic Review in TSCA Risk Evaluations* document.

	neither an explanation nor empirical support for its revisions to the systematic review data quality criteria for epidemiological studies, and certain revisions make it more difficult for epidemiological studies to be scored overall as high quality. Although several limitations of the three human epidemiological studies are presented in the Draft Risk Evaluation, EPA does not provide a convincing argument for outright exclusion of these studies.	EPA/OPPT's quality evaluation method was developed following identification and review of various published qualitative and quantitative scoring systems to inform our own fit-for-purpose tool. The development process involved reviewing various evaluation tools/frameworks (*e.g.*, OHAT Risk of Bias tool, CRED, etc.; see Appendix A of the *Application of Systematic Review in TSCA Risk Evaluations* document and references therein), as well as soliciting input from scientists based on their expert knowledge about evaluating various data/information sources specifically for risk assessment purposes. The epidemiologic criteria were later revised to more stringently distinguish between High, Medium and Low studies. After additional piloting of the criteria, EPA found that the initial iteration of the epidemiologic data quality criteria (as published in the *Application of Systematic Review in TSCA Risk Evaluations*) was inadvertently skewing quality scores toward the tail ends of the scoring spectrum (High and Unacceptable). In order to have the criteria represent a more accurate depiction of the quality levels in the epidemiologic literature, the criteria were revised using two methods. The first method was to make the unacceptable metrics less stringent. This was accomplished by either rewording the metrics to allow for more professional judgement in the interpretation of the unacceptable criterion, or in some cases, completely removing the unacceptable bin from metrics that EPA determined were not influential enough to completely disqualify a study from consideration (mostly metrics in the Analysis and Biomonitoring domain). EPA found that these criteria changes greatly reduced the type one error in the Unacceptable scoring. Acceptable studies were not inaccurately classified as Unacceptable. The second method was to reduce the number of studies that received an overall High rating. Most of overall scores in EPA's initial evaluations during piloting tended to be High. Therefore, EPA strived to revise the criteria to provide more degradation in the scoring to more accurately and objectively distinguish studies of the highest quality from medium and low-quality studies. To do

		this, EPA removed the High criterion from some metrics, particularly in dichotomous metrics (High/Low or High/Unacceptable) that were primarily being binned as High by reviewers across the majority of the studies. These dichotomous metrics were contributing to the overall quality scores being skewed towards High. To address this, EPA shifted some of the dichotomous metrics such that the highest metric score possible (for all studies) is a Medium. The change led to the dichotomous metrics having less significant impact to the numerical scoring and the overall quality rating for each study. With the aforementioned changes to the criteria, EPA observed fewer studies with Unacceptable ratings and more studies shifting from High to Medium, with only the highest quality studies receiving a High overall rating. Out of the ~200 relevant epidemiologic studies and cohorts evaluated for data quality for the first 10 TSCA chemicals, the majority (~80%) still scored as High or Medium. The remaining ~20% of studies scored Low or Unacceptable. EPA is confident that no studies of acceptable quality were inappropriately assigned as Unacceptable. EPA is also confident that the revised criteria bins the quality levels of these epidemiologic studies more appropriately than the previous iteration. Additional refinements to the epidemiologic data evaluation criteria are likely to occur as EPA's validation and process improvement efforts continue.
Need to describe how data was integrated into a final weight of evidence conclusion and why certain studies are eliminated		
SACC, 50, 53, 35, 49	**SACC COMMENTS:** • Improve the clarity of data integration. Multiple times papers that had been identified for data extraction and integration were not used with no explanation as to why. • The explanation of why sources rated "high" were not used needs improvement. This is another example of the difficulty the Committee experienced reconciling information between the SR and the DRE. (page 20) • Under the heading for Executive Summary, 8th bulleted item for conditions of use, page 20, appears to contradict the	In response to comments, EPA has made several editorial changes in multiple sections within the Final Risk Evaluation document (Sections 1, 2, 3, and 4) to increase the transparency of its systematic review process and methodologies used. In addition to the data evaluation criteria published in the *Application of Systematic Review in TSCA Risk Evaluations*, EPA has updated the *Supplemental Information on Occupational Exposure Assessment* to include the strategy that EPA used to integrate occupational exposure data. This data integration strategy can be found in the

	exclusion criteria presented earlier in the Executive Summary. Cleaning and degreasing products were excluded according to the executive summary (page 19) and should be clarified. • Since large percentages of studies are excluded (Section 1.5.1, page 42), the number of items being rejected for each criterion should be summarized to enable readers to determine why studies were excluded. • Consider whether the exclusion of large percentages of studies suggests that the search strategy could be improved. **PUBLIC COMMENTS:** • There is a need for a thorough description and outline of how all evidence and data are integrated into a final weight of evidence conclusion; why some types of studies should receive preference over others in determining the weight of evidence for a particular endpoint. Also, the EPA has not provided justification for using the "hierarchy of preferences" to exclude relevant studies and must detail its approach.	appendix of the updated supplemental document. EPA appreciates the comments and is currently in the process of updating its Systematic Review protocol. In addition, EPA is seeking feedback from the National Academies of Science (NAS) on its Systematic Review process, including data evaluation criteria and data quality rating methods used in TSCA Risk Evaluations. The NAS webinars are currently scheduled from June through August 2020. EPA will consider all comments and feedback received in updating its Protocol. EPA has clarified the Executive Summary language in the Final Risk Evaluation to make clear engine degreasers and brake cleaning products were only evaluated for industrial and commercial use.
SACC	**SACC COMMENTS:** • 1-BP_SR Supplemental File for Data Quality Evaluation of Environmental Fate and Transport Studies indicates the rationale for downgrading the quality rating for a key reference on hydrolysis half-life, namely "Mabey, W; Mill, T. (1978). Critical review of hydrolysis of organic compounds in water under environmental conditions [Review]. J Phys Chem Ref Data 7: 383-415. HERO ID: 9848" was quoted as "Article not useful without cited reference". The missing reference (Laughton, 1959) is readily available and located on page 85 within the Reference section of this document.	The Data Quality Evaluation rating for "Mabey, W; Mill, T. (1978). Critical review of hydrolysis of organic compounds in water under environmental conditions [Review]. J Phys Chem Ref Data 7: 383-415. HERO ID: 9848" has been upgraded after a reevaluation considering the Laughton, 1959 reference.
ECHA Criticisms		
34, 35, 47	**PUBLIC COMMENTS:** • It appears that the ECHA study summaries completely bypassed the data screening step of the literature search process. EPA claims ECHA dossiers are existing chemical assessments equivalent to EPA and ATSDR governmental assessments; however, ECHA dossiers are compilations of	The ECHA studies were not subject to screening since the study summaries were not used in the Final Risk Evaluation. In the Problem Formulation and Draft Risk Evaluation, EPA utilized the results of the environmental hazard data summaries presented in the ECHA database in the quantitative assessment of risks to aquatic species in an attempt to utilize all reasonably available data

	industry information submitted to ECHA that have not been evaluated for quality or reliability by ECHA or any other governmental entity. For EPA to equate them with EPA and ATSDR assessments is simply wrong. EPA holds these industry groups to a different (and lower) standard than institutions.	for 1-BP to create the most robust possible assessment. Following the publication of the Problem Formulation and Draft Risk Evaluation documents, EPA was unable to identify a US data owner for these studies or obtain the full study reports. As a result, the data presented in the ECHA study summaries could not be submitted for data quality evaluation. To reduce uncertainty about the limited environmental hazard data for 1-BP, the Ecological Structure Activity Relationships (ECOSAR; v2.0[2]) predictive model was utilized in the Final Risk Evaluation to further characterize potential hazards to aquatic species from exposure to 1-BP. The use of this modeling program is a common practice for the environmental risk assessment of new and existing chemical substances.
Need for better transparency		
50, 35, 47	**PUBLIC COMMENTS:** • Protocols for all review components need to be determined before conducting the review to minimize bias and ensure transparency in decision making, specified as best practice by all established method. Also, EPA cannot rationally rely on unvetted industry submissions, and to the extent EPA relies on voluntary submissions from industry, EPA must take numerous additional steps to increase their reliability and transparency. EPA needs additional transparency in identification of key studies.	All studies used in the Risk Evaluation, including industry submissions, are evaluated using the same data quality criteria under the TSCA Systematic Review process described in the document, *Application of Systematic Review in TSCA Risk Evaluations*. In consideration of comments received, EPA is in the process of updating the TSCA Systematic Review protocol to improve the transparency of this review process and further reduce possible bias such that all studies are appropriately considered.
Need to better establish methodology of systematic review; need to follow best practices		
SACC, 24,35, 47, 49, 53	**SACC COMMENTS:** • Improve clarity and explanation when data identified during the literature search from one topic is relevant and used for a different topic. Consider improvements to the search terms to ensure relevant data is found. • Ensure all sources of information used in the DRE undergo the systematic review and be explicit where they are derived from. • Studies should be retained even if they are not appropriate for dose-response. For example, animal models with only one concentration may still have useful information.	Based on comments received and challenges experienced with EPA's/OPPT's process, for the first round of Risk Evaluations, EPA is revising it systematic review process for added transparency and clarity. EPA/OPPT's systematic review and quality evaluation method was developed following identification and review of various published qualitative and quantitative scoring systems specifically for the TSCA Risk Evaluation process . The development process involved reviewing various evaluation tools/frameworks (*e.g.*, OHAT Risk of Bias tool, CRED, etc.; see Appendix A of the *Application of Systematic Review in TSCA Risk Evaluations* document and references therein), as well as soliciting

[2]More information about the ECOSAR model can be found at: https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model

	• Improve the use of "grey literature" and peer review literature. As in past DREs, this DRE has government studies in the "peer reviewed literature." • Consider defining or further describing data that are "only considered potentially relevant data/information sources and were used qualitatively" within the SR. **PUBLIC COMMENTS:** • The TSCA systematic review process is inconsistent with best practices in systematic review and is inconsistent with IRIS method, OHAT and Navigation Guide. EPA continues to apply a flawed systematic review method despite serious concerns raised by commenters and the SACC and even summarized in a recent peer-reviewed commentary published in the American Journal of Public Health. • EPA failed to follow necessary internal and external peer-review procedures in developing this process. A critical missing piece in the TSCA method is creating protocols for all review components before conducting the review to minimize bias and ensure transparency in decision making. Other elements of the method not consistent with best practices include non-empirically based "scoring" system, use of metrics not relevant to study quality (reporting), and exclusion of relevant studies. • EPA must address SACC comments on Pigment Violet 29 and incorporate the recommended changes to its systematic review methodology prior to finalizing the 1-BP evaluation and for future TSCA risk evaluations.	input from scientists based on their expert knowledge about evaluating various data/information sources specifically for risk assessment purposes. Current revisions to improve transparency and clarity of the systematic review include more detail, specificity, and data integration. The revised systematic review process is also going through a more intense peer review through the National Academy of Sciences.
35, 50	**PUBLIC COMMENTS:** • EPA should update the general systematic review guidance document to reflect any broadly applicable changes and additional information as it is developed. EPA is changing the rules of how they conduct their 'systematic review" as it goes along and not applying its own method consistently across risk evaluations. Labels are different, included studies may or may not be listed, and there is no clear protocol. This is directly in opposition to the Risk Evaluation Rule in which EPA emphasized the that a clear and transparent systematic	

	review process as being integral to the risk eval process.	
25	**PUBLIC COMMENTS:** • EPA appears to have not performed a full data evaluation/data extraction/data integration according to the systematic review principles for TSCA. EPA does not appear to have applied the data evaluation criteria for in vitro studies or did not publish the evaluation.	In finalizing the Risk Evaluation, EPA has performed data evaluation on additional in vitro genotoxicity studies in accordance with the procedures outlined in the *Application of Systematic Review in TSCA Risk Evaluations*. The evaluation score for key studies have been added to Table_Apx J-4 of the Final Risk Evaluation. In addition, these additional evaluation results will be published in the supplemental files that accompany the Final Risk Evaluation.
Input related to sample size		
SACC	**SACC COMMENTS:** • The names for the criteria should match what they are. For example, "sample size" for occupational studies should be renamed to reflect it is about statistical description. • Also, from the SACC report: In regard to "Sample size," the Committee noted this designation's definition (U.S. EPA 2018a) is not an actual sample size, but whether there are statistical derivations to describe the sample size. They also noted that there is no established process to obtain an unacceptable score. Some Committee members recommended this element be renamed to reflect the definition. (page 20)	EPA will clarify this metric in the revised TSCA Systematic Review protocol. EPA acknowledges that the sample size metric for evaluating occupational exposure data reflects how well the statistical distribution of samples are characterized, rather than the size of the sample.
Consider the following Recommendations from the 2017 1-BP Literature Strategy document:		
SACC	**SACC COMMENTS:** • Correct page 5 and page 8 of the strategy document where the text "ERROR! Reference not found" appears. • Include atmosph* in the search terms for exposure, engineering, & fate on page 22 of the strategy document (Table_Apx B-1). • Verify that Appendix C2 page 30 entry 1013 - Office of Air: Ambient Water Quality Criteria Docs – is accurate. Is this entry associated with the Office of Water? • Page 69, Table E1 indicates that Environmental persistence data were included if they were: "Studies that indicate persistence, transformation, AND degradation in the environment." Should this be OR? Similar comment for Bioaccumulation. • Page 80. It is unclear if the 4th inclusion criterion: "The	EPA will consider these comments during revisions to future literature search strategy documents. The literature search for the first 10 chemicals was conducted in consistency with EPA's existing systematic review process.

	paper is a publicly available document," means that the document can be downloaded without a subscription or if this means published in journal, book, or other outlet that can be accessed with or without cost. This should be clarified.	
Additional SACC Recommendations		
SACC	**SACC COMMENT:** • Consider including groundwater and sediment routes of exposure. One Committee member noted that the literature review for fate and transport data consisted of only atmospheric routes and should also have included groundwater and sediment routes of exposure. . . . The same Committee member noted that the assessment should include this aspect OR state clearly that individuals consuming groundwater are likely to experience higher exposures than estimated by this assessment. (page 22)	EPA considered the groundwater and sediment routes of exposure by examining reported releases to water and modeling of environmental fate. The systematic review of the 1-BP fate and transport literature included queries to capture information on 1-BP groundwater and sediment routes of exposure. However, no reasonably available information on 1-BP groundwater or sediment fate or monitoring values in sediment groundwater was identified. Instead, EPA considered the occurrence and magnitude of TRI reported environmental releases to water. Available TRI reporting for 1-BP releases to water have been consistently low with reported releases of 1-BP of 5 pounds (2016), 1 pound (2017), and 1 pound (2018). Also, EPA incorporated an additional assessment of the sediment compartment in the Risk Evaluation. Estimated screening level surface water concentrations resulting from TRI releases combined with estimated environmental partitioning using a Level III Fugacity model was used to address 1-BP risk to sediment dwelling organisms. The details are provided in Sections 2.1 Fate and Transport, 3.1 Environmental Hazards, and 4.1 Environmental Risk.

Occupational Exposure Assessment		
Charge Question 2.1: Please comment on the approaches and estimation methods, models, and data used in the occupational exposure assessment. **Charge Question 2.2:** Please provide any specific suggestions or recommendations for alternate data, or estimation methods that could be considered by the Agency for conducting the occupational exposure assessment.		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 2**	**EPA/OPPT Response**
EPA conflates the risk evaluation and risk management processes by assuming use of personal protective equipment (PPE)		
34, 54	**PUBLIC COMMENTS:** • TSCA intentionally divides risk evaluation and risk management into two distinct processes, whereby regulatory measures are considered after EPA finds an unreasonable risk. By choosing to make risk determinations based on the assumption of universal, effective use of PPE, EPA conflates risk evaluation and risk management and leads EPA either not to find unreasonable risk or to underestimate the magnitude of that risk in a number of scenarios – thereby denying itself the authority to impose mandatory requirements sufficient to control workplace exposures. If PPE is not taken into account, inhalation MOEs are below the benchmark MOE by up to three orders of magnitude for virtually all workers and ONUs.	EPA agrees that there are challenges associated with use of PPE; they are described in Section 5.1.1.3. By providing risk estimates that account for use of PPE, EPA is not recommending or requiring use of PPE. Rather, these risk estimates are part of EPA's approach for developing exposure assessments for workers that relies on the reasonably available information and expert judgment. When appropriate, EPA will develop exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. EPA did assess the risk to workers in the absence of PPE, and those risks are presented in Section 4 Risk Characterization under Table 4-57, Occupational Risk Summary Table. While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA has also outlined its PPE assumptions in Section 5.1.
Assumption that workers are provided with PPE, properly trained to use PPE, will use PPE, and that PPEs are effective		

SACC, 24, 27, 30, 34, 46, 47, 48, 49, 51, 54	**SACC COMMENTS:** • EPA's DRE should acknowledge exposures can occur if individuals are unaware of the proper procedures or engineering controls during their work process. The post engineering controls discussion as written in the DRE implies that workers and ONUs will properly use engineering controls and work processes. (page 31) • Communicate the limitations of the assumption that proper PPE is used and comment on the potential effect of incorrect or lack of PPE use on the risk estimates. This will assist users of this risk assessment in tailoring their professional judgment to fit their specific scenario. • Communicate the limitations of the assumption that PPE provides effective protection and comment on the potential effect of the failure of PPE on the risk estimates. This will assist users of this risk assessment in tailoring their professional judgment to fit their specific scenario. • Be mindful of work scenarios where the tech spray study assumption may not apply and cite the MMWR case report as an example of a deviation from this assumption. This will help readers of the risk assessment better apply the assessment findings to their particular work situation. **PUBLIC COMMENTS:** • The assumption that workers will use PPE even when such equipment is not required, provided, or used is not realistic. o EPA acknowledges that PPE (a) is not always used (*e.g.*, p. 57, p. 205), (b) may not always be used correctly (*e.g.*, p. 134), and (c) often does not provide complete protection even when it is used correctly (*e.g.*, p.106). o EPA acknowledges that the use of respirators on a continuous, long-term basis may not be practical due to respirators being uncomfortable, interfere with communication, limit vision, and make it hard to breathe. o EPA has stated elsewhere in the draft risk evaluation that (i) few literature sources indicate the use of	EPA's approach for developing exposure assessments for workers is to use reasonably available information and expert judgment. When appropriate, in the Risk Evaluation, EPA will use exposure scenarios both with and without PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. Again, while EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on reasonably available information and professional judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address uncertainty. Use of the high-end value also accounts for the exposure to PESSs. In the Risk Evaluation, EPA provides several explanations of the assumptions regarding the use of PPE in the workplace. Section 2.3.1.3 discusses the hierarchy of controls, including PPE considerations, while Section 4.2 communicates the limitations on the assumption of PPE use. Specifically, Section 4.2.2 states that respirators must be properly worn and fitted in order to be effective, and presents information where EPA believes respirator use is plausible. Section 4.2.4.1 further communicates the limitations on assuming PPE use in chronic exposure scenarios. With respect to the limitations of glove use, EPA's assumptions and methodology for estimating dermal risks are described in Section 2.3.1.23, including assumptions about glove use and associated protection factors. The data about the frequency of effective glove use – that is, the proper use of effective gloves – is very limited in

	respirators in 1-BP conditions of use and (ii) EPA does not know the actual frequency, type, and effectiveness of glove use in specific workplaces with 1-BP conditions of use. ○ No supporting data available that PPE is universally used. ○ EPA itself rejected respirator use as a worker protective strategy in its proposed TSCA rules banning use of trichloroethylene (TCE) in aerosol and vapor degreasing operations.	industrial settings. Initial literature review suggests that there is unlikely to be sufficient data to justify a specific probability distribution for effective glove use for a chemical or industry. Instead, the impact of effective glove use is explored by considering different percentages of effectiveness. EPA also considered potential dermal exposure in cases where exposure is occluded. See further discussion on occlusion in Appendix J of the Supplemental File: Information on Occupational Exposure Assessment.
26, 47, 48	**PUBLIC COMMENTS:** ○ Use of PPE can still result in 1-BP exposure: Breakthrough of 1-BP can occur through the carbon or other medium in organic vapor cartridges in respirators. This is not discussed in the draft risk evaluation. Tanaka et al (1999) provides an equation that predicts 1-BP breakthrough within ~117 minutes. ○ Not all glove materials provide protection against 1-BP, with OSHA stating that 1-BP easily travels through most glove materials. ○ Gloves can increase skin temperature and humidity, which can increase absorption. Therefore, the assumption that glove protection factors can only range as low as 1x (no gloves) is erroneous; rather, the range should include PFs below 1x.	
34, 47, 48	**PUBLIC COMMENTS:** • There is evidence that training and safety data sheets (SDSs) are not sufficient to ensure use of protective measures: ○ Review of SDSs for 1-BP have found that many SDSs do not specify the type of gloves that workers should use. ○ Significant evidence demonstrates that SDSs are often of insufficient quality to be useful and are frequently not understood (Nicol et al., 2008; Hodson et al., 2019). ○ Workers observed to use incorrect glove types and frequently lack an adequate understanding of breakthrough time when using protective gloves. ○ Case studies available of workers not using PPE (CDC	EPA agrees that SDSs are not sufficient to ensure use of PPE. In the Risk Evaluation, EPA does not assume that the inclusion of PPE on SDSs is sufficient to ensure PPE use. And, while EPA considers the information on SDSs, EPA does not make PPE use assumptions based solely on SDS.

	reports).	
26	**PUBLIC COMMENTS:** • It is inappropriate, in the absence of any required OSHA controls on 1-BP, to assume that employers will provide respirators to their workers. The SACC should encourage EPA to cease the practice of diluting risk estimates based on unwarranted assumptions about respirator use. EPA should work with OSHA to evaluate the more precautionary and more scientifically valid set of Assigned Protection Factors (APFs) developed circa 1999-2002, before OSHA decided to change the APFs to make them less protective.	EPA bases its assumptions regarding use of respirators in the workplace on reasonably available information and professional judgment. In Section 4.2.2 of the Final Risk Evaluation, EPA included additional information on whether respirator use is plausible for each condition of use and recognized that respirator use is unlikely for certain conditions of use, such as those uses that occur in small commercial facilities.
54	**PUBLIC COMMENTS:** • EPA assumes employers will provide respirators up to an Average Protection Factor (APF) or 50, which often requires a full face-piece. However, employers select respirators by comparing only the measured employee exposure with the PEL. For example, if measured exposures are 10 ppm and OSHA asserts 1-BP exposures should remain below 1 ppm, the employer need only select a respirator with an APF of 10.	The inclusion of varying levels of protection factors associated with use of PPE (both gloves and respirators) is provided to characterize risk. When appropriate, in the Risk Evaluation, EPA uses exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. For the purposes of determining whether a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on the reasonably available information and professional judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties.
26	**PUBLIC COMMENTS:** • EPA should not construct "post engineering controls" scenarios to hypothesize what exposures to 1-BP might be if there are not any OSHA or EPA requirements to actually install engineering controls.	The post-engineering control exposure scenarios presented in the Risk Evaluation reflect exposure levels in specific workplace conditions where an engineering control or equipment substitution takes place and are meant to characterize risk. EPA acknowledges there may be variability in post-engineering control exposure levels at different facilities and workplaces, depending on what specific control is implemented.
Incorrect interpretation of OSHA's authorities and requirements		

26, 34, 46, 47, 49, 54	**PUBLIC COMMENTS:** • EPA confirms 1-BP worker exposures are substantially higher than NIOSH and ACGIH recommended exposure limits, yet wrongly assumes employers are required to provide respirators to their workers. EPA cites OSHA's Respiratory Protection Standard (29 CFR 1910.134), but that standard only requires respirator use when ambient workplace concentrations exceed an OSHA PEL (Permissible Exposure Limit, PEL). There is no OSHA PEL for 1-BP nor is there likely to be one in the foreseeable future. • The General Duty Clause (GDC) permits OSHA to cite an employer exposing employees to significant risks of harm recognized by the employer, however the requirements of OSHA's Respiratory Standard are not triggered, and employers have no duty to provide respirators to employees unless OSHA can show each element of the GDC violation exists. Even if citations were issued, the Respiratory Standard requires employers implement engineering controls / respirator use only to the extent necessary and does not require employers to reduce exposures to a level that satisfies TSCA's requirement of avoiding unreasonable risk. • OSHA PPE regulations apply only where the employer has determined that workers are subject to sufficient hazards from chemical exposures where necessary, and employers have considerable latitude in deciding whether a hazard exists. Even if government bodies such as EPA's IRIS or National Toxicology Program classifies a chemical as a carcinogen, a company can weigh the evidence differently using its own methodology. An example is the 2015 Dow Chemical SDS for methylene chloride.	For the purpose of this Risk Evaluation, EPA makes assumptions about potential PPE use based on reasonably available information and professional judgment. EPA considers each condition of use and constructs exposure scenarios with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a condition of use presents unreasonable risks, the use of PPE assumptions are outlined in Section 5.1 and described in the unreasonable risk determination for each condition of use, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA acknowledges that the OSHA regulations at 29 CFR 1910.132 require employers to assess a workplace to determine if hazards are present or likely to be present which necessitate the use of personal protective equipment (PPE). If the employer determines hazards are present or likely to be present, the employer must select the types of PPE that will protect against the identified hazards, require employees to use that PPE, communicate the selection decisions to each affected employee, and select PPE that properly fits each affected employee.
34, 47	**PUBLIC COMMENTS:** • OSHA's database of inspections demonstrates that even for chemicals with an OSHA PEL, noncompliance and violations of the respiratory standard were the 4th most common type of violation in OSHA inspections in 2018.	EPA agrees that non-compliance with an OSHA PEL is an enforcement issue for OSHA. OSHA data are collected as part of compliance inspections at various types of facilities. Certain industries are typically targeted based on national and regional emphasis programs. Other inspections may be prompted based on complaints or referrals. As a result, OSHA data may underrepresent PPE usage throughout the affected industry. To account for uncertainties and variabilities in PPE usage in its unreasonable risk

		determinations, EPA uses the high-end exposure values.
34, 47	**PUBLIC COMMENTS:** • EPA implies that safety data sheet recommendations for PPE are mandatory (p. 289), when in fact, OSHA's standard mandating SDSs specifically states there is "no requirement for employers to implement the recommended controls."	In Section 5 of the Final Risk Evaluation, EPA has revised the narrative and format to provide better clarity on the basis for the unreasonable risk determinations. EPA does not assume that the inclusion of PPE on SDSs is sufficient to ensure PPE use and while EPA considers the information on SDSs, EPA does not make PPE use assumptions based solely on SDS.
The selection of models, inputs, and default assumptions used are not well explained or are incorrect		
25, 50	**PUBLIC COMMENTS:** • EPA's use of Models requires a robust sensitivity analysis – initial exposure models should be derived from sensitivity analyses and used to identify exposure parameters and assumptions with most uncertainty while higher-tiered models should be used to refine more realistic exposure evaluations. EPA should more clearly note assumptions within each model, especially in dermal exposure calculations where model inputs are not supported by the weight of scientific evidence. EPA should provide more discussion and justification for model inputs and assumptions.	EPA has conducted a sensitivity analysis for each model to evaluate how the input parameters affect modeling results. The default value and assumptions associated with each input parameter is explained in detail in the Supplemental File: Information on Occupational Exposure Assessment, which was published along with the Draft Risk Evaluation. EPA has also included additional justifications for the dermal exposure model inputs, including the hand surface area, quantity remaining on skin, and fraction absorbed parameters in the Final Risk Evaluation.
38	**PUBLIC COMMENTS:** • Assumptions do not represent real-world conditions. Ventilation controls, for example, are not considered within any of the inhalation models, likely leading to exposure overestimates.	The occupational inhalation exposure models utilize air exchange rates for actual facilities associated with the scenario assessed. These values represent ventilation systems in real-world conditions and are detailed in the Supplemental File: Information on Occupational Exposure Assessment.
25	**PUBLIC COMMENTS:** • There is inconsistency in the dermal models used between consumer and occupational exposure, with consumer exposure using the permeability model and occupational exposure using fraction absorbed model. • EPA should consider a range of compositions for loading tasks in the Tank Truck and Railcar Loading and Unloading Release and Inhalation Exposure Model. EPA currently assumes 1-BP is present at 100% concentration while some companies have reported formulations containing 1 to 30% 1-BP.	In response to comments received, consumer dermal exposure was expanded to include two models (permeability and fraction absorbed) based on the expected exposure scenario for a given condition of use. Even though consumer exposure was evaluated with a fraction absorbed model, there are some inherent differences between the approaches to occupational and consumer dermal exposure based on the unique conditions under which an occupational worker receives dermal exposure compared to the consumer. Differences include consideration of PPE use (gloves that are protective against 1-BP) for occupational workers and a better characterized time component for consumer due to more refined duration of use/exposure. EPA includes a discussion of the various dermal models used for occupational and consumer

		exposure estimates in Sections 2.3.1. and 2.3.2. EPA has updated the *Tank Truck and Rail Car Loading and Unloading Release and Inhalation Exposure Model* to consider a range of concentrations as reported in the 2016 CDR. The revised model considers formulations containing 30 percent 1-BP for the central-tendency scenario.
26	**PUBLIC COMMENTS:** • In only 2 of the 20 worker scenarios are the central-tendency estimates of exposure greater than the overall mean of 20 ppm (sprayers and non-sprayers in adhesives use). It is hard to understand how the overall measured mean exposure could be 29 ppm when so few of the separate scenarios have medians above 10 ppm. EPA should check whether the mean and high-end exposures were underestimated in the other 18 scenarios.	The inhalation exposures in each occupational scenario reflect the different workplaces where 1-BP is manufactured, processed, and used including variable use patterns, engineering controls, and different ventilation systems. This results in a variety of exposure scenarios, where workers at some facilities have higher inhalation exposures than others.
31	**PUBLIC COMMENTS:** • The amount of 1-BP used in the US is overestimated due to double or triple counting, for example, double counting occurs when 1-BP use is reported by both the formulator and the manufacturer.	The 1-BP volume presented in the Draft Risk Evaluation is based on volumes reported by industry in the 2016 CDR. EPA has discussed the potential double counting issue with the commenter, and welcomes CDR submitters to correct their reports, where appropriate.

47	**PUBLIC COMMENTS:**
	• EPA assumptions related to occupational non-users (ONUs) are not necessarily realistic as follows:
	  ○ ONUs may not stay within their "far field zone"
	  ○ ONUs may not have exposures distinct from workers in small dry-cleaning operations or other industries with relatively small workspaces
	  ○ Workers and ONUs may regularly pass into each other's space
	• For EPA's dermal exposure estimates, EPA collapsed 12 use subcategories into a single bin, "Aerosol Spray Degreaser/Cleaner, Other Aerosol and Non-aerosol Uses" (p. 234). The 12 use subcategories are highly diverse, ranging from hobby materials to construction materials to laboratory chemicals and should not be collapsed together. No rationale was provided for this.
		EPA has revised the Risk Evaluation to discuss uncertainties associated with assumptions related to ONUs. EPA acknowledges that workers and ONUs may not stay within their respective work zones for the entire workday, and that exposures for ONUs can vary substantially. Most data sources do not sufficiently describe the proximity of these employees to the exposure source. As such, exposure levels for the "ONU" category will have high variability depending on the specific work activity performed. It is possible that some employees categorized as "ONU" have exposures similar to those in the "worker" category depending on their specific work activity pattern. ONUs are likely a heterogeneous population of workers, and some could be exposed more than just occasionally to high concentrations.
		
		The exposure scenarios for the purpose of dermal exposure modeling are binned based on the activity pattern and potential exposure levels. The rationale and assumptions for "binning"

		multiple exposure scenarios for the dermal modeling are explained in the Supplemental File: Information on Occupational Exposure Assessment.
27, 31, 47, 51	**PUBLIC COMMENTS:** • Data sets used by EPA need to be made publicly available. The OSHA 2019 occupational exposure data are not currently available. For vapor degreasing, the actual data used to develop exposure concentrations are not presented and the links for all but one of the references for open top degreasers do not work. The one reference with a working link (Reh and Nemhauser, 2001) have data that are not consistent with those shown in Table 2-19. Caution should also be used because occupational exposure data collected in one setting may not be applicable to workers in another occupational setting.	EPA has updated the HERO links to include exposure monitoring data provided by the OSHA. In consultation with OSHA, certain data elements have been masked to protect personally identifiable information (PII).
Draft Risk Evaluation is missing conditions of use, pathways and routes of exposure, repeated-use scenarios, and additional considerations		
SACC	**SACC COMMENTS:** • Consider the exposure variability can result in error from the estimate and not specify the direction of the error. • Consider that instantaneous releases into the near field is a realistic exposure scenario for dry cleaners. • Another Committee member noted on page 87, under the heading for Supplemental Information from the Occupational Exposure Assessment that EPA discussed using a constant emission scenario and pointed out that exposures likely vary over time. The risk evaluation suggested this can result in an overestimate of exposures. The member recommended that the direction of this error should not be specified because while an overestimate is possible, an underestimate is also possible. It all depends on the specific scenario and the magnitude of the variability. If the magnitude of the variability is extreme, then an "average" constant emission assumption could conceivably also be an underestimate. (page 28)	EPA appreciates the recommendations and has considered and/or addressed the uncertainties and variabilities in the Final Risk Evaluation, where appropriate. For example, EPA has acknowledged in Section 4.3. that variability can result in either an under- or over-estimate.
47, 48, 51	**PUBLIC COMMENTS:** • Draft risk evaluation is missing conditions of use such as: ○ Processing of 1-BP for use as a recyclable reaction	EPA reviewed the comments to determine if conditions of use were missing. After a discussion with the commenter, EPA determined that the processing of 1-BP as "recyclable reaction solvent" was not

	solvent. This condition of use can be listed as a "reaction solvent" under "processing – incorporation into formulation, mixture or reaction product" in Table 1-4. ○ Use of 1-BP in spray foam blowing. This was identified to EPA early on in the development process for the risk evaluation. EPA has not provided any rationale for its exclusion as a condition of use. ○ Use of 1-BP as a flame retardant. This was identified to EPA early on in the development process for the risk evaluation. EPA has not provided any rationale for its exclusion as a condition of use. ○ Spills in the workplace, particularly exposure of maintenance staff who clean up spills and leaks.	a condition of use of 1-BP under TSCA. EPA has not found that 1-BP is intended, known, or reasonably foreseen to be used for spray foam blowing, although 1-BP is used in another type of insulation (rigid board insulation). This condition of use was included in the Draft Risk Evaluation for off-gassing from rigid board insulation. The Final Risk Evaluation includes an updated exposure scenario for the commercial use of 1-BP in insulation. <u>Spills/Leaks</u> Spills and leaks generally are not included within the scope of a TSCA risk evaluation. EPA is exercising its authority under TSCA to tailor the scope of the Risk Evaluation for 1-BP, rather than evaluating activities which are determined not to be circumstances under which 1-BP is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, or environmental exposure pathways addressed by another EPA-administered statute and associated regulatory program. First, EPA does not identify 1-BP spills or leaks as "conditions of use." EPA does not consider 1-BP spills or leaks to constitute circumstances under which 1-BP is manufactured, processed, distributed, used, or disposed of, within TSCA's definition of "conditions of use." Congress specifically listed discrete, routine chemical lifecycle stages within the statutory definition of "conditions of use" and EPA does not believe it is reasonable to interpret "circumstances" under which 1-BP is manufactured, processed, distributed, used, or disposed of to include uncommon and unconfined spills or leaks for purposes of the statutory definition. Further, EPA does not generally consider spills and leaks to constitute "disposal" of a chemical for purposes of identifying a COU in the conduct of a risk evaluation. In addition, even if spills or leaks of 1-BP could be considered part of the listed lifecycle stages of 1-BP, EPA has "determined" that spills and leaks are not circumstances under which 1-BP is

		intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, as provided by TSCA's definition of "conditions of use," and EPA is therefore exercising its discretionary authority under TSCA Section 3(4) to exclude 1-BP spills and leaks from the scope of the 1-BP Risk Evaluation. The exercise of that authority is informed by EPA's experience in developing scoping documents and Risk Evaluations, and on various TSCA provisions indicating the intent for EPA to have some discretion on how best to address the demands associated with implementation of the full TSCA Risk Evaluation process. Specifically, since the publication of the Risk Evaluation Rule, EPA has gained experience by conducting ten Risk Evaluations and designating forty chemical substances as low- and high-priority substances. These processes have required EPA to determine whether the case-specific facts and the reasonably available information justify identifying a particular activity as a "condition of use." With the experience EPA has gained, it is better situated to discern circumstances that are appropriately considered to be outside the bounds of "circumstances… under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" and to thereby meaningfully limit circumstances subject to evaluation. Because of the expansive and potentially boundless impacts that could result from including spills and leaks as part of the Risk Evaluation, which could make the conduct of the Risk Evaluation untenable within the applicable deadlines, spills and leaks are determined not to be circumstances under which 1-BP is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, as provided by TSCA's definition of "conditions of use." Exercising the discretion to not identify spills and leaks of 1-BP as a COU is consistent with the discretion Congress provided in a variety of provisions to manage the challenges presented in implementing TSCA Risk Evaluation. See *e.g.,* TSCA Sections 3(4), 3(12), 6(b)(4)(D), 6(b)(4)(F). In particular, TSCA Section 6(b)(4)(F)(iv) instructs EPA to factor into TSCA Risk Evaluations "the likely duration, intensity, frequency, and number of exposures under the conditions of use…," suggesting that activities for which

		duration, intensity, frequency, and number of exposures cannot be accurately predicted or calculated based on reasonably available information, including spills and leaks, were not intended to be the focus of TSCA Risk Evaluations. And, as noted in the preamble to the Risk Evaluation Rule, EPA believes that Congress intended there to be some reasonable limitation on TSCA Risk Evaluations, expressly indicated by the direction in TSCA Section 2(c) to "carry out [TSCA] in a reasonable and prudent manner." For these reasons, EPA is exercising this discretion to not consider spills and leaks of 1-BP to be COUs. Second, even if 1-BP spills or leaks could be identified as exposures from a COU in some cases, these are generally not forms of exposure that EPA expects to consider in the risk evaluation. TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a Risk Evaluation, to identify the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations the Agency "expects to consider" in a Risk Evaluation. As EPA explained in the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" ("Risk Evaluation Rule"), EPA may, on a case-by-case basis, tailor the scope of the risk evaluation "in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33729 (July 20, 2017). In the Problem Formulation documents for many of the first 10 chemicals undergoing Risk Evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA...." The approach discussed in the Risk Evaluation Rule and applied in the problem formulation documents is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the Risk Evaluation on areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520.

		In addition to TSCA Section 6(b)(4)(D), the Agency also has discretionary authority under the first sentence of TSCA Section 9(b)(1) to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator." TSCA Section 9(b)(1) provides EPA authority to coordinate actions with other EPA offices, including coordination on tailoring the scope of TSCA Risk Evaluations to focus on areas of greatest concern rather than exposure pathways addressed by other EPA-administered statutes and regulatory programs, which does not involve a risk determination or public interest finding under TSCA Section 9(b)(2). Following coordination with EPA's Office of Land and Emergency Management (OLEM), EPA has found that exposures of 1-BP from spills and leaks fall under the jurisdiction of RCRA. Solid wastes containing 1-BP may be regulated as a hazardous waste under the RCRA waste code D001 (ignitable liquids, 40 CFR 261.21(a)(1)). As a result, EPA believes it is both reasonable and prudent to tailor the TSCA Risk Evaluation for 1-BP by declining to evaluate potential exposures from spills and leaks, rather than attempt to evaluate and regulate potential exposures from spills and leaks under TSCA.
26, 34, 48, 49	**PUBLIC COMMENTS:** • Draft risk evaluation is missing the following pathways and routes of exposure: The rationale for their exclusion is either not provided or not valid. • Oral route of exposure not considered at all. • "Take home exposures," whereby the family of a worker, including children, may be exposed via contact with the worker's contaminated clothing or skin.	EPA generally does not evaluate occupational exposures through the oral route. Workers may inadvertently transfer chemicals from their hands to their mouths or consume contaminated food. The frequency and significance of this exposure route are dependent on several factors including the p-chem properties of the substance during expected worker activities, workers' awareness of the chemical hazards, the visibility of the chemicals on the hands while working, workplace practices, and personal hygiene that is difficult to predict. Similarly, the frequency and magnitude of take-home exposure is dependent on several factors, including personal hygiene and visibility of the chemical on skin or clothing. EPA does not have methods to reliably predict take-home exposure.
30, 47	**PUBLIC COMMENTS:**	EPA acknowledges that assuming one unloading event per day

	• EPA assumes a single exposure event per workday or only one container loaded per day. Workers come into repeated contact with the chemical throughout their workday or have more than one loading activity per day. This leads to an underestimation of worker exposure.	creates an uncertainty in the exposure estimation and has noted this uncertainty in the Risk Evaluation. The Risk Evaluation assumes one container is loaded each day over 260 working days per year throughout the working years, and that the activity is performed by the same worker. At some facilities, container loading/unloading may be performed by different workers, such that the same worker is not exposed each day. These assumptions could lead to either an underestimation or overestimation.
47	**PUBLIC COMMENTS:** • Certain conditions of use are oversimplified, leading to missing considerations, such as: o For (i) processing as a reactant, (ii) processing – incorporation into articles, (iii) repackaging, and (iv) disposal and recycling, EPA uses the Tank Truck and Railcar Loading and Unloading Release and Inhalation Exposure Model that assumes only activities of loading and unloading. These conditions of use have additional activities beyond loading and unloading which were not considered in EPA's evaluation. o For open top, manual vapor degreasers, it has been observed that workers manually place baskets into these open-top vapor degreasers and may receive substantial dermal and respiratory exposures when leaning over the degreaser and breaking the vapor blanket. EPA does not appear to have taken some of these hazards into account in the risk evaluation.	In developing the Risk Evaluation, EPA conducted a comprehensive literature search following TSCA Systematic Review procedures to identify exposure data related to 1-BP conditions of use. Where monitoring data are reasonably available, EPA used actual workplace exposure monitoring data to assess exposure to workers and occupational non-users. The exposure monitoring data for vapor degreasing covers a distribution of exposure levels and includes manual activities where a worker may be exposed to high 1-BP concentrations. Where exposure monitoring data are not reasonably available, EPA used modeling approaches to estimate exposure. For example, EPA developed the *Tank Truck and Railcar Loading and Unloading Release and Inhalation Exposure Model* to estimate exposure during container loading activities – a source of exposure applicable to several conditions of use. Each model makes certain simplifying assumptions and it is not always possible to model all potential worker activities across all facilities covered under that condition of use. EPA acknowledges that modeled exposure estimates could have a certain degree of uncertainty and has noted these uncertainties in the Risk Evaluation.
Concerns related specifically to the vapor degreaser scenario		
31	**PUBLIC COMMENTS:** • All vapor degreasing methods are combined into Bin 2 where it is stated that these "are not closed systems." This is incorrect because there are closed loop systems that are often used in vapor degreasing. The bins should be separated into open top and closed loop systems as the dermal exposures would be expected to be different between these two types of degreasers.	EPA acknowledges that workers will not be in direct contact with 1-BP during degreaser operation. However, even in the case of closed-loop systems, workers may still have contact with the solvent during equipment troubleshooting and maintenance activities. In addition, the conditions of use were grouped into bins based on the maximum expected concentration of 1-BP in the formulation. Since similar formulations can be used across different degreaser types, all vapor degreasing uses are grouped into the same

	• For closed-loop degreasers, where there is no exposure to 1-BP to the atmosphere during the process, neither the source data nor the NEWMOA (2001) values that EPA used to determine the 1-BP concentrations in the breathing zone are based on actual air measurements. The modeling should be presented with a range of potential reductions, which could result in air concentrations below levels of detection.	"bin." EPA is not able to present a modeled range of potential reductions, since EPA has not identified additional reasonably available information to determine what range of exposure reduction should be modeled.
23	**PUBLIC COMMENTS:** • We have recorded the results of over 200 discrete air monitoring studies that document real world workplace exposures to nPB. Although the contents of our nPB exposure database is confidential and not available for public release, we have compiled the results of the individual studies to build an extensive exposure database gathered from workers using both open-top and closed-loop vapor degreasers. MicroCare disagrees with the Draft EPA assessment of risk determination for closed loop type batch vapor degreasers. Of a total of eight individual 8-hour time weighted dosimeter studies from our database, the results for five tests came back between 00.0 ppm to <1.0 ppm…this category should be listed as "Does not present an unreasonable risk of injury to health (workers and occupational non-users)."	EPA is not able to evaluate the aforementioned exposure data, as they have not been submitted to the Agency. However, EPA notes that risks are present even when 1-BP exposure levels are below 1 ppm as 8-hr TWA, which is the same range provided by the commenter in their summary of the data provided during the comment period for the Draft Risk Evaluation.
29	**PUBLIC COMMENTS:** • Albemarle conducted an occupational exposure study in an aerospace wiring assembly plant which employed two back to back vapor degreasers. Exposure levels below the level of detection (<0.2 ppm) were observed, which demonstrates that ventilation in conjunction with the proper use of personal protective equipment can be used to significant effect in reducing exposure to 1-BP or other chemicals.	EPA has reviewed the exposure data provided the commenter. These data have been evaluated through the TSCA Systematic Review process and integrated into the Final Risk Evaluation.
29	**PUBLIC COMMENTS:** • EPA states that exposure levels of .025, .033, and .017 ppm cannot be achieved even while wearing an APF = 50 respirator for an operator using the commonly used models of Branson-style vapor degreasers. Using the NIOSH standard method for 1-BP, the limit of detection is 0.2 ppm, which is above EPA's target exposure levels.	As stated in the Risk Evaluation, the cancer inhalation unit risk (IUR) is 0.004/ppm. This IUR value translates to a 1-BP airborne concentration of approximately 0.06 ppm as 8-hr TWA, and a calculated lifetime average daily concentration (LADC) of 0.025 ppm for central tendency occupational exposure scenarios. NIOSH Analytical Method 1025 has an estimated limit of detection

		(LOD) of 1 microgram per sample for 1-BP. This method has been demonstrated to reliably measure airborne concentrations of 1-BP as low as 0.01 ppm over a full work shift. OSHA has developed and partially validated PV2061 for 1-BP, which has an LOD of 0.13 ug per sample and a reliable quantitation limit of 0.007 ppm. Both methods are capable of quantifying 1-BP airborne concentrations at or below 0.06 ppm 8-hr TWA.
Occupational (worker) or OSHA related concerns		
SACC	**SACC COMMENTS:** • Use caution in its use of N-acetyl-S-(n-propyl)-L-cysteine (BPMA) as a biomarker for 1-BP exposure in the general population until EPA scientists can carefully consider its utility as a biomarker in general population exposure studies. It would be useful for the risk assessment document to contain references and describe the points and counter points so that readers can make their own decision. Detail how other compounds can be metabolized to BPMA. In contrast, these biomarkers may be useful in occupational studies where you have a clear, relatively high magnitude (*e.g.*, above background), and specific known exposure to 1-BP. • Focus on occupational non-users (ONU's) exposures which may be underestimated by assuming high efficacy of post-engineering control. • Clarify that time weighted exposures are averaged over 8 and 12 hours respectively and indicate they are not following the OSHA extended shift policy. • Consider ONU's to include any workers who might be affected who work in co-located facilities that can be impacted by vapor migration and intrusion. • Better describe the estimates of exposed workers by stating that they are "less precise," rather than specifying the direction of the potential error. • Consider additional exploration of OSHA compliance data or compliance/inspection reports to see if they can ascertain additional information about the prevalence of improper and proper use of engineering controls in workplaces. • On Page 87 under the heading for Supplemental Information from the Occupational Exposure Assessment, EPA indicates	For the purpose of the 1-BP Risk Evaluation, EPA is not using N-acetyl-S-(n-propyl)-L-cysteine as a biomarker. As noted by the SACC, N-acetyl-S-(n-propyl)-L-cysteine is also a metabolite of several other compounds. The uncertainties associated with various biomarkers of exposure are discussed in Section 3.2.4 of the Risk Evaluation. EPA carefully reviewed each recommendation. In finalizing the 1-BP Risk Evaluation and accompanying supplemental documents, EPA made several revisions to better characterize the uncertainties in the exposure estimates, the direction of bias, and the TWA calculations. In particular, EPA agrees that assuming ONUs remain in their respective work zone could lead to an underestimate. EPA also acknowledges that 1-BP is more volatile than TCE, such that there is uncertainty in assuming 90 percent exposure reduction in the post-engineering control scenario. In addition, in response to comments, EPA has included additional information on a NIOSH survey on actual respirator use in the workplace. However, in the Final Risk Evaluation, EPA is not considering 1-BP exposure to workers at co-located facilities that may be impacted by vapor migration and intrusion.

	that the post-engineering control assuming a 90% reduction is based on Trichloroethylene (TCE). A Committee member pointed out that the Agency should recognize that 1-BP behaves differently and is a more volatile chemical, which can impact the effectiveness of controls. (page 31) • Reconsider assumption about exposure zones with respect to estimating ONU exposure • A Committee member noted on page 86, under the heading for Supplemental Information from the Occupational Exposure Assessment, that EPA's assumption that the occupational worker remains in their respective exposure zones may over-estimate their exposure. While this is true for the worker, it should also be highlighted that it may underestimate the occupational nonuser's (ONUs) exposure. (pages 27-28)	
Clarification, documentation, and limitations related to modelling		
SACC	**SACC COMMENTS:** • Provide more details about documentation for models • Clarify the formula for acute concentration and each of its variables. The model description provided in a supplemental document should be provided in the body of the DRE. • Further refinement of the dermal model is not needed for this evaluation. EPA should evaluate and comment on the potential limitations of this model and discuss the potential for underestimation in the dermal absorption assessment. Errors in the estimates resulting from experimental conditions of the studies used in their assessment should be carefully considered and communicated in the risk assessment. • EPA should be clear on how and where documentation for models used for exposure assessment can be found if the risk evaluation is to be transparent and results reproducible. Model documentation or details not included in the risk assessment or supplemental information should reference resources or links should be provided for the reader to obtain those details as needed. (page 29)	Due to the length of the information, it is not possible to present all the model documentation within the body of the Risk Evaluation. EPA presents the details on occupational exposure estimates, including exposure calculations, formulas, and model documentation in the Supplemental File: Information on Occupational Exposure Assessment. In consideration of SACC comments, EPA has also evaluated the effect of experimental conditions on the measured fractional absorption – a parameter used in the occupational dermal exposure model. In the Final Risk Evaluation, the fractional absorption value has been adjusted to account for wind speed likely to be encountered at workplaces.
Additional Recommendations		

SACC	**SACC COMMENTS:** • Provide references to the source of these initial estimates. • Explicitly note the limitation in these estimation methods and communicate reasonable confidence limits on these estimates or a range of values they believe are reasonable. In addition, EPA should consider updating these estimates over time to assure the estimates most accurately reflect current practice. • Re-evaluate the estimates to assure they are reasonable and as accurate as possible. • Acknowledge an implied assumption may not be true in practice, so that any person using this risk assessment understands that this assumption has been made and this assumption may not hold in real practice. This would help the user of this risk assessment make informed judgements. • EPA should be clear that these assumptions about vapor capture efficiency are uncertain and that any user of this risk assessment should be aware that this is an area of uncertainty that can greatly impact the risk estimates. • Consider further evaluation of what percent reduction is likely by additionally assessing other compounds with similar vapor pressures and behavior. At a minimum, EPA should clearly describe the potential error in estimation that can occur by using TCE as the model compound. • Reconsider description of constant emission scenario.	EPA has carefully reviewed each recommendation. In finalizing the 1-BP Risk Evaluation, EPA made several revisions to better document and characterize the model input values, assessment assumptions, uncertainties, limitations, and their impact on the resulting exposure estimates. For example, EPA has revised the Final Risk Evaluation and supplemental file regarding its characterization of the constant emission scenario as an overestimate, as recommended by SACC. At this time, EPA does not have additional quantitative data on the potential exposure reduction that can be achieved when installing different ventilation systems on vapor degreasers.
26	**PUBLIC COMMENTS:** EPA should be using means (arithmetic averages), not medians, to characterize the central tendency of exposure.	EPA's current approach is consistent with the Agency's 1992 Guidelines for Exposure Assessment (EPA/600/Z-92/001), which states that both arithmetic mean (average) and median are measures of the central tendency of exposure distribution.

Consumer Exposure Assessment

Charge Question 3.1: Please comment on the approaches, models, exposure or use information (*e.g.*, information on duration, number of user events, amount used) and estimates for the nine consumer uses evaluated for this Draft Risk Evaluation.
Charge Question 3.2: Please provide any specific suggestions or recommendations for alternative approaches, models, exposure or use information (*e.g.*, information on duration, number of user events, amount used) that could be considered by EPA in developing and /or refining the exposure assumptions and estimates for the nine consumer uses evaluated for this Draft Risk Evaluation.
Charge Question 3.3: Dermal exposure was evaluated using a permeability method within CEM based on the availability of a permeability coefficient found within the literature in a study by NIOSH. The permeability method within CEM does not consider evaporation when estimating exposure which is the primary basis for EPA evaluating dermal exposure only for consumer uses where there is a continuous supply of product against the skin during use or a barrier prohibiting evaporation. Please comment on the chosen approach and provide any suggestions or recommendations for alternative approaches, dermal methods, models, or other information which may guide EPA in developing and refining the dermal exposure estimates.

#	Summary of Peer Review Comments for Specific Issues Related to Charge Question 3	EPA/OPPT Response
The selection of inputs and default assumptions used in each modeling scenario are not well explained		
25, 50	**PUBLIC COMMENTS:** • EPA's use of Models requires a robust sensitivity analysis – initial exposure models should be derived from sensitivity analyses and used to identify exposure parameters and assumptions with most uncertainty while higher-tiered models should be used to refine more realistic exposure evaluations. EPA should more clearly note assumptions within each model, especially in dermal exposure calculations where model inputs are not supported by the weight of scientific evidence. EPA should provide more discussion and justification for model inputs and assumptions.	EPA expanded its discussion of assumptions within the Final Risk Evaluation on both approaches used and model inputs. EPA also expanded its consumer dermal modeling to include all conditions of use (except insulation off-gassing). EPA's consumer exposure model (CEM) includes a detailed sensitivity analysis in the accompanying user guide and user guide appendices. EPA considered the CEM sensitivity analysis in its selection of parameters to vary across a range of exposure parameters to cover a spectrum of possible consumer exposure scenarios. EPA also revised dermal model inputs, where applicable, to utilize a neat value, rather than aqueous-based value. EPA did a comparison of results across three dermal models and conducted a more detailed sensitivity analysis of the dermal models used in the Final Risk Evaluation. Additionally, EPA provides an explanation of the model selection for the Final Risk Evaluation. MCCEM and IECCU are both peer reviewed models and provide a more robust, condition of use specific, exposure evaluation.

Dermal exposure should be modeled using the fraction absorbed model, consistent with dermal occupational exposure		
50	**PUBLIC COMMENTS:** • EPA should use the fraction absorbed models, rather than permeability models, to assess dermal exposure so that evaporation is not ignored.	EPA revised its dermal modeling approach to include both fraction absorbed and permeability models within the Final Risk Evaluation along with a comparison of the results between models. Models were applied based on expected exposure scenarios within a given condition of use. For example, EPA retained use of the permeability model for the coin and scissors cleaner condition of use because use of the products likely involve full immersion of body parts into the product during use which is more appropriately modelled with the permeability model (due to a constant supply of product against the skin and no evaporation from the skin during immersion).
25, 38	• There is inconsistency in the dermal models used between consumer and occupational exposure, with consumer exposure using the permeability model and occupational exposure using fraction absorbed model.	In response to comments received, consumer dermal exposure was expanded to include two models (permeability and fraction absorbed) based on the expected exposure scenario for a given condition of use. Even though consumer exposure was evaluated with a fraction absorbed model for certain conditions of use, there are some inherent differences between the approaches to occupational and consumer dermal exposure based on the unique conditions under which an occupational worker receives dermal exposure compared to the consumer. Other differences include consideration of PPE use (gloves that are protective against 1-BP) for occupational workers and a better characterized time component for consumer due to more refined duration of use/exposure. EPA includes a discussion of the various dermal models used for occupational and consumer exposure estimates in Section 2.3.1 and 2.3.2.
Draft Risk Evaluation is missing conditions of use, pathways and routes of exposure, and endpoints		
47, 48	**PUBLIC COMMENTS:** • Draft risk evaluation is missing conditions of use that were excluded during problem formulation, such as adhesives in consumer products (except as an adhesive accelerant for arts and crafts) and engine degreasing or brake cleaning in consumer products. There are no sources or supporting data cited or provided to justify this exclusion. The sources EPA lists in Table 2-2 to support these exclusions, in fact, do the opposite. In addition, many chemical formulations designed for workplace use are available	As explained in the problem formulation, 1-BP is not present in final non-pesticidal agricultural products; therefore, those products are not included in the risk evaluation. However, the use of 1-BP as reactant in non-pesticidal agricultural products is included in the risk evaluation. Similarly, 1-BP is not present as adhesive in consumer products; therefore, the products evaluated are adhesives in commercial settings only. The adhesive accelerant for arts and crafts available to consumers was evaluated. Commenters have stated, correctly, that "many chemical formulations designed for workplace use are available for purchase online by

	for purchase online by individuals. While some uses are not currently ongoing, these uses have not been banned and may be used again.	individuals." EPA's research found a small number of 1-BP-based consumer products available for purchase on consumer purchasing platforms. Current adhesives containing 1-BP are (1) not sold through consumer channels, (2) not marketed to consumers, (3) not sold in quantities usable by consumers, and (4) not recommended for consumer use. Furthermore, EPA has not found reasonably available information that products containing 1-BP are used for engine degreasing or brake cleaning by consumers, because the cost of such a product is prohibitive for consumers compared to similar products that are marketed to consumers.
26,34, 39, 47, 48, 49	**PUBLIC COMMENTS:** • Draft risk evaluation is missing the following pathways and routes of exposure. The rationale for their exclusion is either not provided or not valid. o Releases to water and land not considered at all. o Releases to ambient air. EPA's evaluation incorrectly assumes a background concentration of zero for 1-BP. However, there is considerable evidence (*e.g.*, recent TRI data) that 1-BP emissions are a significant pathway of exposure for the general population and are additive to the exposure of 1-BP that occurs from use of consumer products. EPA indicated that 1-BP would be adequately assessed under the Clean Air Act (CAA) because it will be listed as a Hazardous Air Pollutant (HAP). However, 1-BP is currently not listed as a HAP even though EPA was petitioned ten years ago to list it, and there is no mandated date to decide whether to grant or deny the petition. Even if 1-BP were listed as a HAP, through the CAA, EPA would mandate technology-based – not risk-based – emission limits and they would only apply to "major" sources and not the large number of smaller establishments that account for substantial 1-BP emissions. CAA requirements would also not	Releases to water were considered during the scoping phase but, based on the analysis at that time, were not further analyzed due to very low release numbers reported to water (5 pounds of the 20 million pounds manufactured or processed in a single year). Even with this low release to water, additional discussion was added to the environmental exposure and general population sections to discuss releases to water and associated exposure. EPA considered the occurrence and magnitude of TRI reported environmental releases to land. Solid wastes containing 1-BP may be regulated as a hazardous waste under RCRA waste code D001 for ignitable liquids (40 CFR 261.21). 1-BP may also be co-mingled with solvent mixtures that are RCRA regulated substances. These wastes would be either incinerated in a hazardous waste incinerator or disposed to a RCRA Subtitle C hazardous waste landfill. Some amount of 1-BP may be improperly disposed as municipal wastes in RCRA Subtitle D landfills, although they are likely to be a small fraction of the overall waste stream. 1-BP migration from RCRA Subtitle C landfills or RCRA Subtitle D municipal landfills will be mitigated by landfill design (double liner, leachate capture for RCRA Subtitle C landfills and single liner for RCRA Subtitle D municipal landfills) and requirements to adsorb liquids onto solid adsorbent and containerize prior to disposal. As stated in the Problem Formulation, releases to RCRA Subtitle C and Subtitle D landfills were not included in this Risk Evaluation.

	consider the combined impact of air emissions and other sources of exposure. ○ Existing exposure pathways already subject to regulation. Existing regulatory standards may not be adequate to protect human health and the environment. ○ Existing conditions of use already subject to regulation. Existing regulatory standards may not be adequate to protect human health and the environment. ○ Vapor or mist deposition onto skin or via direct liquid contact during use. While included in the problem formulation, EPA has not provided justification for its exclusion in the draft risk evaluation or addressed the uncertainty it imparts to its dermal exposure assessment. ○ Disposal of consumer products. EPA provides no evidence that most products will be disposed of in original containers and that liquid products may be recaptured in an alternate container following use. Even if an alternate container is used, the collection and disposal process may lead to consumer exposure.	There may be some confusion when trying to directly link releases to ambient air with EPA's selection to assume a background concentration of zero when evaluating consumer exposure to 1-BP in the indoor environment. While ambient concentrations may marginally impact indoor air concentrations, by far the largest contributor to consumer exposure to a chemical during consumer use of a product inside a residence is the use of the product itself and any overspray which may occur during use. Residual chemical remaining within the indoor environment after use could also impact overall exposure if the decay rate of the chemical is very long. However, in the case of 1-BP, the high vapor pressure and volatilization of the chemical following use was found to be approximately 6 hours to 12 hours residence time. Considering the short use durations and low frequency of use during a given year (based on survey data on product use), residual chemical after use also has a very marginal impact on overall exposure. As explained in more detail in Section 1.4.2 of the risk evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA. EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several

		concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment. EPA investigated the capability of its existing models to provide output files associated with vapor-to-skin dermal exposure, however, we have identified some limitations with providing such estimates within the current model constructs. While vapor to skin may have a minor contribution to overall dermal exposure (as noted by SACC), the high volatility of 1-BP is expected to cause the chemical to remain in the vapor phase and available for inhalation exposure rather than re-depositing onto the skin causing a vapor-to-skin dermal exposure. Products in two conditions of use (coin and scissors cleaner and automobile AC flush) were evaluated using an assumption that the product is placed/captured in an "alternate" container (placed in a bowl during use for the coin and scissors cleaner product and captured in a bucket for the automobile AC flush product). The durations of exposure are assumed to include both application/use of the product as well as time to carry/transfer in preparation for disposal. However, EPA has not identified any information or evidence which may inform the actual disposal actions/pathways which may be utilized by the consumer for these two products. Remaining products are assumed to be fully used prior to disposal and therefore the only disposal item would be the empty container within which the product originally came (spray bottle, aerosol can, etc.).
49	**PUBLIC COMMENTS:** • EPA's evaluation of risks to consumers only examines end-points – acute reproductive and developmental effects – that are relevant to women of child-bearing age and fetuses. However, expanding the evaluation to include multiple-exposure scenarios and general	Consumer inhalation exposure was evaluated for both consumer users and bystanders. Additionally, the inhalation exposures were concentration based, and independent of age and other exposure factors (respiration rates, etc.). Therefore, the exposure estimates are applicable to any age group, including children, women of reproductive age, and the elderly. Although the consumer user of these high solvent products is not assumed to include infants or certain other

	population exposure from air emissions would require EPA to include other endpoints that can harm infants and children, men of reproductive age and other groups that are now excluded from EPA's assessment of risks to consumers.	susceptible populations, a bystander exposure (also evaluated in the Draft and Final Risk Evaluations) can represent exposure to members of any age group that are not users and are present in the residence during product use.
Chronic exposures to 1-BP through consumer use is not addressed		
47, 49	**PUBLIC COMMENTS:** • EPA assumes a single exposure event per day for consumer exposure and assumes that exposure will never be chronic in nature. As such, chronic exposure to 1-BP for consumers is not assessed. Chronic exposure may occur from repeated use scenarios such as: o Consumers who may be do-it-yourselfers who may use products more frequently or may use more than one product within a single day. o Off-gassing of stored consumer products inside the home. o 1-BP insulation exposures installed in homes. 1-BP from use in insulation is expected to be present in living areas at above 2 µg/m3 for almost 150 days and will persist in the living area well beyond 400 days.	EPA revised the Risk Evaluation for the insulation (off-gassing) condition of use. EPA applied both a short-term and long-term duration of exposure as well as evaluating acute and chronic exposure (Section 2.3.2.1) However, for all other consumer uses, EPA assumes that exposure is not chronic in nature, the assumption is discussed in Section 2.3.2.6 of the Risk Evaluation. EPA directly identifies the uncertainties, such as exposure estimates may underestimate exposure to individuals who are involved with do-it-yourself projects as well as recognition that consumer practices are moving toward more do-it-yourself work. The consumer use exposure scenario did not evaluate off-gassing from stored products as storage of a product cannot be linked to a condition of use evaluated and is not in and of itself identified as a consumer condition of use within the scope of the Risk Evaluation. Additionally, TSCA Section 6(b)(4)(F)(iv) instructs EPA to factor into TSCA risk evaluations "the likely duration, intensity, frequency, and number of exposures under the conditions of use." This suggests that activities for which duration, intensity, frequency, and number of exposures cannot be accurately predicted or calculated based on reasonably available information were not intended to be the focus of TSCA Risk Evaluation. Since reasonably available information was not identified to inform these and other parameters (including off-gassing rates or concentrations) and as recognized by SACC that the absence of data leaves it uncertain how to develop a worst-case scenario, storage of consumer products was not evaluated in this Risk Evaluation.
Certain conditions of use scenarios and modeling input parameters are not realistic or are outdated		
25, 50	**PUBLIC COMMENTS:** • EPA should use realistic scenarios in its conditions of use for consumer products – 1-BP is rarely found in	EPA's efforts to identify realistic conditions of use for consumer products are presented in Section 2.3.2.1. This section provides a discussion of the approach and search efforts implemented to identify

	consumer products.	conditions of use applicable to consumers. The approach utilized identified multiple consumer products containing 1-BP which are readily available for purchases. The Draft and Final Risk Evaluation evaluated those conditions of use where 1-BP containing products are available for purchase and use by a consumer and EPA found evidence of consumer use based on marketing and price of similar products used by consumers. EPA therefore modeled as consumer products some products that are marketed to commercial and industrial users but are sometimes used by consumers.
25, 50	**PUBLIC COMMENTS:** • Model input parameters are overly conservative and appear to capture products intended for industrial/commercial uses with appropriate PPE. EPA should use plausible and current information to inform parameters and assumptions, including duration of use, mass of product used, and amount of chemical in the product formulation. For example, the source (Westat Survey) EPA used for a number of model parameters was conducted more than 30 years ago. As SACC members noted, consumer use patterns have changed significantly since 1987.	The Draft and Final Risk Evaluation evaluated those conditions of use where 1-BP containing products are available for purchase and use by a consumer. This included some 1-BP containing products intended for industrial/commercial uses, but those products were are also marketed to consumers for use. EPA used the same approach to remove as a condition of use certain degreasing products that were not available to consumers (*i.e.*, engine degreasers) in the Draft Risk Evaluation. While these specific engine degreasing products were available for purchase by the consumer, EPA did not find evidence of consumer use. Therefore, those products were not evaluated for consumer exposure, although still evaluated for industrial/commercial uses. Sections 2.3.2.2 and 2.3.2.6 provides a discussion about the Westat Survey and the assumptions and uncertainties associated with use of the Westat Survey (including age of the survey), respectively. While some consumer use patterns may have changed somewhat, most of the products evaluated for this Risk Evaluation fit well within the categories identified by the Westat Survey including the expected durations of use and mass used. Additionally, while the Westat Survey is more than 30 years old, SACC members also noted that it is a very good survey and the best available data and supported its use. Further, the Westat Survey was rated as a high-quality study under EPA's systematic review process. Finally, to help minimize potential biases to a high-end exposure scenarios for certain durations or mass used, EPA chose to evaluate consumer exposure across a spectrum of durations/mass used including the 10^{th}, 50^{th}, and 95^{th} percentile data as identified within the Westat Survey.
31	**PUBLIC COMMENTS:** • The amount of 1-BP used in the US is overestimated	The amount of 1-BP used in the US does not directly impact consumer exposure as consumer exposure is based on the amount of chemical

	due to double or triple counting, for example, double counting occurs when 1-BP use is reported by both the formulator and the manufacturer.	within a known product which is not linked to the total amount used in the US. This is especially true given that almost all use of 1-BP is industrial and commercial use. The amount used by a consumer is based on the Westat Survey data which provides mass used of a given product (which was then cross-walked with the conditions of use evaluated in this Risk Evaluation).
Insulation scenario modeled needs further consideration		
SACC	**SACC COMMENTS:** • Expand the description of inclusion of insulation off-gassing under consumer exposures to better describe these exposures or capture under General Population exposures.	The insulation (off-gassing) condition of use was expanded for the Final Risk Evaluation to include two different building configurations, acute and chronic exposure, and an analysis of the impact of temperature on off-gassed concentrations. This better represents the expected exposure to consumers installing the insulation product within their residence.
45	**PUBLIC COMMENTS:** • The Polyisocyanurate Insulation Manufacturers Association provided additional clarification on typical end use applications for rigid board insulation products. Rigid board insulation products are most commonly used as exterior insulation (*e.g.*, roofs, walls, foundations, basements). This means that the installed product is separated from the interior space by other building components (*e.g.*, structural sheathing, interior drywall, concrete). While rigid board insulation products may be used to insulate the interior spaces of buildings, other insulation products (commonly referred to as "wall cavity insulation") are more frequently used. Where used within interior spaces, most rigid board insulation products are required by building code to be separate from the interior space by a thermal (fire) barrier (*i.e.*, drywall). Certain classes of rigid board insulation products may be installed as exposed interior finishes where permitted by the building code.	EPA appreciates the comment and additional information provided. EPA considered it for the revisions to the insulation (off-gassing) condition of use within the Final Risk Evaluation. Section 2.3.2.4 of the Final Risk Evaluation provides a more detailed description of the insulation board product utilizing 1-BP in its formulation as well as the revised approach to evaluating consumer exposure to 1-BP from insulation (off-gassing).
47	**PUBLIC COMMENTS:** • EPA did not analyze consumer exposures in houses with basements containing insulation made with 1-BP. According to the National Association of Homebuilders, the majority of new homes in the US	In response to both SACC and public comments, EPA's revised approach includes a second building configuration which includes a full basement. Section 2.3.2.4 of the Final Risk Evaluation provides a more detailed description of the revised approach to evaluating consumer exposure from insulation (off-gassing).

	are built with basements.	
47	**PUBLIC COMMENTS:** • EPA assumed that living areas are not insulated based on a study of spray insulation, which resulted in EPA calculating very high margins of exposure for consumer exposures in living areas. However, EPA's condition of use for 1-BP is only for rigid board insulation, so it is unclear how relevant use patterns for spray foam insulation would be to the use of insulated boards.	Section 2.3.2.4 of the Final Risk Evaluation provides a more detailed description of the revised approach to evaluating consumer exposure from insulation (off-gassing). Within this section, EPA notes that while spray foam insulations are used by consumers, EPA's investigation into 1-BP containing products did not identify any consumer spray foam insulation products (either fibrous or foaming) which included (or identified) 1-BP within its formulation. Unlike other conditions of use evaluated, the insulation (off-gassing) condition of use did not rely on consumer use patterns identified within the Westat Survey, but rather assumed a one-time installation of rigid insulation board in the attic and crawlspace (and basement). The area of coverage is discussed in Section 2.3.2.4.
Recommendations to improve the TSCA exposure assumptions and estimates for consumer uses		
SACC	**SACC COMMENTS:** • Adjust the consumer use patterns of this category in the Westat Survey to better reflect current uses. There may also be adjustments to the related occupational use patterns. • Assess consumer exposures and/or potential sensitive sub-populations. • Confirm the existence (or non-existence) of referenced products before finalizing the risk evaluation. • Expand the PESS description and analysis with respect to consumer exposures. The Committee discussed this concern in greater detail under Charge Question 6.6. • Supplant the Westat Survey whenever possible and encourage updating or repeating the Westat Survey. • The Committee encouraged a similar treatment of uncertainty to the extent possible.	EPA has revised the discussion of uncertainties associated with 1-BP containing products in Section 2.3.2.6, and some additional context on PESS is provided in Section 2.4 of the Final Risk Evaluation. The absence of recent surveys or other data on consumer use patterns limits EPA's ability to adjust consumer use patterns utilized for this evaluation. EPA has, however, been considering other possible avenues to obtain more recent consumer use pattern information for future Risk Evaluations, but was unable to implement them for this current evaluation for 1-BP. Along similar lines, while supplanting, updating, or repeating the Westat Survey is a possibility in the future, to develop such a survey is a long-term project requiring multiple reviews and approvals outside of the TSCA framework (*i.e.*, paperwork reduction act, information collection authorities, etc.). EPA's approach to evaluating consumer exposure indirectly considers exposure of potentially exposed or susceptible sub-populations by including evaluation of inhalation exposure to bystanders within the residence and following use of a 1-BP containing consumer product. To EPA's knowledge, the existence of referenced products remains

		relatively unchanged since initial product identification. Additionally, most conditions of use have multiple products associated with the condition of use and therefore, even if some products have since been removed from commerce, the range of products remains applicable within the Risk Evaluation by considering weight fractions across multiple products within a given COU.

Environmental Hazard and Risk Characterization		
Charge Question 4.1: Only a few environmental test data endpoints (including ECHA) are available in the public domain for 1-BP. Most are from the ECHA website. EPA attempted to obtain the full ECHA studies with no success. Since the studies were in French and Japanese (and no U.S.A. sponsor), EPA decided not to make further attempts to find the studies. Given that the ECHA environmental test data results are in the public domain, EPA decided to use the environmental data. Please comment on the reasonableness of this approach for the environmental hazard assessment of 1-BP. **Charge Question 4.2**: EPA determined that there are no environmental risks based on a screening-level assessment of risk using environmental hazard data, TRI exposure data, fate information, and physical/chemical properties. Please comment on the approach used in the screening-level assessment. Are there other data that EPA could have considered? If so, please provide specific data and references.		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 4**	**EPA/OPPT Response**
Ecological toxicity data from ECHA database summaries are inadequate to determine that 1-BP presents no unreasonable environmental risk		
30, 34, 47, 49, 53	**PUBLIC COMMENTS:** • EPA cannot reliably determine that 1-BP poses no unreasonable risk based on the ecological toxicity data from the ECHA database summaries. The study summaries used do not contain sufficient information to evaluate study quality or accuracy of the reported findings, were not peer reviewed or validated by ECHA, and can be revised by the companies that submitted them to eliminate inconvenient findings or data at any time.	EPA is not utilizing the results presented in these study summaries in the Final Risk Evaluation. In the Problem Formulation and Draft Risk Evaluation, EPA utilized the results of the environmental hazard data summaries presented in the ECHA database in the quantitative assessment of risks to aquatic species. Following the publication of these documents, EPA was unable to identify a US data owner for these studies or obtain the full study reports. As a result, the data presented in these study summaries could not be submitted for data quality evaluation. The lack of data quality evaluation for these studies results in a high degree of uncertainty indicated in the public and SACC comments received for 1-BP. To reduce this uncertainty, the Ecological Structure Activity Relationships (ECOSAR; v2.0[3]) predictive model was utilized in the Final Risk Evaluation to further characterize potential hazards to aquatic species from exposure to 1-BP. The use of ECOSAR modeling program to predict environmental hazards of 1-BP is appropriate. ECOSAR is commonly utilized for the environmental risk assessment of new and existing chemical substances. ECOSAR used the most robust and data rich chemical class, neutral organics, to predict the environmental

[3]More information about the ECOSAR model can be found at: https://www.epa.gov/tsca-screening-tools/ecological-structure-activity-relationships-ecosar-predictive-model

		hazards to fish, aquatic invertebrates, and algae from acute and chronic exposure to 1-BP. This substantially broadens the available data that can be used to validate the use of the single acute fish toxicity study to characterize the environmental hazards and risks of 1-BP. As explained in Section 3.1.4 of the final risk evaluation, the extensive dataset used to populate this chemical class includes several chemicals that are similar to 1-BP in terms of molecular weight and logK_{OW}. In addition, much of the data used to populate the ECOSAR training set was comprised of data generated as part of the same research effort as the single acute fish toxicity study (Geiger et al., 1988). The acute fish toxicity data and the predicted toxicity values from ECOSAR are consistent in that both indicate that 1-BP presents a moderate environmental hazard (see section **Error! Reference source not found.** of the risk evaluation for a comparison of the available ecotoxicity data with ECOSAR modeling outputs).
34, 47	**PUBLIC COMMENTS:** • EPA must obtain and make public the full studies to allow the public to assess the quality of the studies. Even the best study summaries are incomplete descriptions that do not allow for an independent examination of study quality and conclusions reached by authors. Common examples of such conclusions include, "findings were not statistically significant," "findings are within the range of historical controls," and "effects observed were non-linear [and therefore biologically questionable or irrelevant]." Without actual details and results, it is not possible to evaluate the appropriateness of such conclusions.	EPA acknowledges the uncertainties that arise from the use of ECHA summaries without reviewing the underlying data for data quality in Sections 3.1 and 4.3.4. EPA was unable to identify a US data owner for these studies or obtain the full study reports to submit them for data quality evaluation. As a result, EPA is not utilizing these study summaries in the Final Risk Evaluation. Therefore, the unreasonable risk determination is based on an acute toxicity study with fish that was determined to be of high-quality following data quality evaluation. ECOSAR modeling outputs for 1-BP were also added to further characterize potential hazards to aquatic species from 1-BP.
30, 49	**PUBLIC COMMENTS:** • If full studies are not in English or inaccessible, EPA could have ordered any U.S. manufacturer, processor, or user of 1-BP to conduct its own research into 1-BP's environmental toxicity and to submit the resulting study and data. Since it has long been aware of the limited ecotoxicity data of 1-BP, had EPA required manufacturers to conduct this testing, publicly available test results would now be available for use in the risk evaluation.	EPA was unable to identify a US data owner for these studies and obtain the full study reports to submit for data quality evaluation, EPA is not using these ECHA study summaries in the Final Risk Evaluation. Therefore, the unreasonable risk determination is based on a single acute toxicity study with fish that was determined to be high quality, as well as ECOSAR (v2.0) modeling outputs for 1-BP. The use of ECOSAR to characterize environmental risks is commonly used throughout the chemical assessment process, and is particularly appropriate to characterize

		chemicals when they belong to a particularly robust chemical category such as neutral organic chemicals, which is the case for 1-BP. Considering the collective body of data available for 1-BP, EPA has determined that it has enough information to complete the 1-BP Risk Evaluation using a weight of scientific evidence approach. EPA selected the first 10 chemicals for Risk Evaluations based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this Risk Evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation.
Even the limited ecological toxicity data available do not support EPA's determination of no unreasonable risk		
30	**PUBLIC COMMENTS:** • Of the limited summaries available, one summary reported observations of "lethargy (fish at base of test vessel), darkened pigmentation (body and/or eye orbits), loss of orientation (nose upwards), surface swimming, overturned individuals at base of test vessel, hyperventilation and pale faces with excessive mucus" in fish exposed to 1-BP. Another study similarly reported lethargy in exposed fish.	EPA has decided not to utilize these study summaries in the Final Risk Evaluation since EPA was unable to identify a US data owner for these studies and could not submit them for data quality evaluation. Similar sublethal effects were reported in the single acute fish study presented in the Final Risk Evaluation. Consistent with the OSCPP 850.1075 Freshwater and Saltwater Fish Acute Toxicity Test Guideline[4], any sublethal effects should be reported, but statistical procedures employed to calculate the 96-h LC50 are based on mortality observed during the test.
EPA incorrectly claims ECHA dossiers are existing chemical assessments equivalent to EPA and ATSDR governmental assessments		
34, 47	**PUBLIC COMMENTS:** • EPA claims ECHA dossiers are existing chemical assessments equivalent to EPA and ATSDR governmental assessments. ECHA dossiers are actually not assessments and are not government documents. They are compilations of industry information submitted to ECHA that have not been evaluated for quality or reliability by ECHA or any other governmental entity.	EPA did not utilize the ECHA summaries in the Final Risk Evaluation since EPA was unable to obtain the full studies, which are only available via European entities, and therefore could not analyze the studies directly for data quality evaluation. In the Draft Risk Evaluation, since EPA was unable to obtain the specific studies or the names of the data owners, EPA cited the secondary source from which the data was obtained. EPA acknowledges the uncertainties that arise from using data
47	**PUBLIC COMMENTS:** • EPA cites the dossiers posted on the ECHA website as	

[4] https://nepis.epa.gov/Exe/ZyPDF.cgi/P100SH65.PDF?Dockey=P100SH65.PDF

	"ECHA, [date]" and in EPA's Health & Environmental Research Online (HERO) data system, these entries are listed as the "European Chemicals Agency" as the reference's author. Such text citations and HERO entries are incorrect and misleading. These documents were prepared by the industry registrants, not ECHA, and the information has not been evaluated by ECHA or any other governmental entity. While some chemicals do eventually undergo a "substance evaluation" by government authorities under REACH, 1-BP has not.	summarized in ECHA where the original studies have not been received by EPA or reviewed for data quality in Sections 3.1 and 4.3.4.
Studies used did not undergo the systematic review process		
30, 34, 47	**PUBLIC COMMENTS:** • For the industry-prepared summaries of limited aquatic toxicity testing, the study summaries were not subjected to the systematic review process or other quality review and they bypassed the data screening step of EPA's literature search process.	EPA is not using these study summaries in the Final Risk Evaluation since EPA was unable to identify a US data owner for these studies or obtain the full study reports to submit them for data quality evaluation.
No justification or citation provided to support EPA's acute-to-chronic-ratio (ACR) of 10		
34, 47	**PUBLIC COMMENTS:** • EPA extrapolates from the single study on acute fish toxicity (p. 141) and the industry's acute study summaries to estimate chronic toxicity, by applying an "acute-to-chronic ratio," or ACR, that it sets at 10. EPA provides no justification or citation to support this value. A search of the literature indicates that an ACR of at least 100 may be needed to be sufficiently protective. • From Ahlers et al., 2009, "Only test results in accord with the European Union Technical Guidance Document (TGD) and validated by authorities were considered. Whereas the median ACRs of 10.5 (fish), 7.0 (daphnids), and 5.4 (algae) are well below the ACR safety factor of 100 as implied by the TGD, individual ACRs vary considerably and go up to 4400. The results suggest that a safety factor of 100 is not protective for all chemicals and trophic levels."	EPA acknowledges that there is uncertainty regarding the use of acute-to-chronic extrapolation to estimate hazards from chronic exposure to 1-BP. While an ACR of 10 may not be protective for all chemicals and trophic levels, the use of an acute-to-chronic ratio of 10 is consistent with EPA methodology for the assessment of new chemical substances. EPA considers these ACRs to be protective of aquatic invertebrates from acute and chronic exposures to neutral organic substances such as 1-BP, which produce toxicity from simple narcosis. Additional context has been added to the Final Risk Evaluation to understand the limits of this value in the context of available literature. EPA is in the process of evaluating the body of reasonably available literature on the subject in order to determine whether to revise standards for application of AF and the acute to chronic ratio for the next 20 high-priority substances undergoing risk evaluation. Until the body of scientific evidence for assessment factors is evaluated, EPA will continue to use OPPT methodology as cited in the Draft Risk Evaluation and apply an ACR of 10 to estimate the chronic hazard of the chemical substance from acute

		toxicity data.
49	**PUBLIC COMMENTS:** • EPA calculated an ACR of 10 by relying on the ECHA summaries of acute studies. Without independent verification of the ECHA summaries and the studies they describe, there is no assurance that the chronic toxicity value EPA derived was correct.	EPA acknowledges the uncertainties that arise from using environmental hazard data summarized in ECHA. These study summaries were not used in the Final Risk Evaluation since EPA was unable to identify a US data owner for these studies or obtain the full study reports to submit them for data quality evaluation. .
EPA's approach and methodology for assessing environmental exposure ignores or over-simplifies fate characteristics, ignores key data, and uses values that lack transparency or may not be suitable		
47	**PUBLIC COMMENTS:** • Values used in the draft risk evaluation (Table 1-1, p. 28), either were sourced from textbooks or were estimated using EPISuite. The values sourced from textbooks are not original data; therefore, the quality of the studies (or models) and the underlying data must be evaluated before they are used in a risk evaluation.	Data evaluation tables for 1-BP physical-chemical properties studies are included in the supplemental files for the 1-BP Risk Evaluation. EPA evaluated the quality of the data cited in sources such as the *Merck Index* using data quality metrics and data evaluation scoring described in *Application of Systematic Review in TSCA Risk Evaluations.* These include metrics that are designed to take the QC processes and overall quality of gray literature sources such as the *Merck Index* into account when assessing the quality of the data. The physical-chemical properties for 1-BP taken from the *Merck Index* all scored as having a high overall quality level.
	• The water solubility value (which is variously described as being "high" (pp. 23, 140, 186, 188, 246, 249, 258), "moderate" (p. 51), and "low" (p. 337) is sourced from Yalkowsky et al. 2010; however, that textbook in turn references a study conducted in 1917 (Horiba 1917), which, in turn, is actually referencing data from 1906. Yalkowsky et al. noted in their data evaluation that the purity of solute, equilibrium time/agitation, and analysis were all not provided by Horiba, which indicates these data are not reliable. Given the importance EPA has placed on water solubility in determining risk, this value must be scrutinized before being used to dismiss hazard, exposure potential, or risk.	Water solubility descriptors have been standardized. In its data evaluation EPA considers many data quality metrics to derive an overall data quality score. Where experimental details are missing, studies are considered of lower quality; however, unless studies were scored to be unacceptable, they could still be used with caution and proper characterization.
	• Physical-chemical property models in EPISuite lack transparency in performance and applicability. The property model performance estimations are only presented in terms of overall performance and do not describe whether or not the model is applicable for any specific chemical.	EPI Suite™ has undergone detailed review by a panel of EPA's independent Science Advisory Board (Science Advisory Board (SAB) Review of the Estimation Programs Interface Suite (EPI Suite™) Sept 7, 2007 EPA-SAB-07-11). Individual physical-chemical estimation programs and/or their underlying predictive

	Disclaimer statements are found in each program that uses quantitative structure property relationships (QSPR). These examples illustrate that this, and other, EPISuite property models lack transparency as to their appropriateness for application to 1-BP.	methods and equations have been described in numerous journal articles in peer-reviewed technical journals. The full reference citations are given in the Help files for the individual programs. 1-BP estimated values were calculated using methods derived from measured properties of a set of chemicals including halogenated alkanes. The EPISuite™ Help files contain links to the chemical datasets used to develop each estimation method.
	• EPA used partition coefficients, which assume chemical equilibrium. However, exposure to chemicals of concern can occur in high concentrations in different environmental compartments prior to reaching equilibrium. Additionally, when considering an open, multi-media system, a better approximation might be the Level III Fugacity model, which predicts 10% of 1-BP will be distributed to soil, 44.7% to air, 45.2% to water, and the remainder (0.1%) to sediment, as calculated using EPISuite 4.11. A 10% percent distribution to soil cannot be automatically dismissed as de minimis.	The environmental risk characterization has been updated to include fugacity estimations and discussion.
	• EPA over-relies on limited and incomplete data, including from TRI, to exclude or dismiss the significance of numerous exposure pathways. The TRI 2016 data EPA used were from the first year the chemical was required to be reported, with only ~40% of expected facilities reporting data – this fact was largely ignored when citing TRI data as the basis for excluding exposure pathways or asserting low release or exposure to 1-BP. The agency ignored additional categories of TRI releases reported for 1-BP in 2017 that had not been reported in 2016, including nearly 8,000 pounds of 1-BP reported as "other land disposal," which is described as "such activities as placement in waste piles and spills or leaks"76 and approximately 14,500 lbs. to "other off-site management."	EPA does not expect significant concentrations of 1-BP in water or sediment based on limited discharges to water and physical-chemical properties of 1-BP. In the Problem Formulation, EPA explained that the systematic review process did not identify studies/data confirming the presence of 1-BP in surface water, ground water or drinking water. TRI information from reporting year 2016 indicated that 1-BP was released to two locations in quantities of 1 lb/year and 4 lbs/year. And EPA estimated surface water concentrations well below the COC even when using a conservative approach. Subsequent reporting years (2017, 2018) have followed a similar trend with 1 lb/year or less being released to water by a single facility, thus these discharges rates are similar to the 2016 reporting.,
Environmental exposure pathways that would contribute to ecotoxicity were not considered or were dismissed without justification		
47	**PUBLIC COMMENTS:** • EPA excluded the air pathway, indicating that 1-BP would be adequately assessed under the Clean Air Act because it will be listed as a Hazardous Air Pollutant (HAP).	As explained in more detail in Section 1.4.2 of the Final Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media,

	However, 1-BP is currently not listed as a HAP even though EPA was petitioned ten years ago to list it, and there is no mandated date to decide whether to grant or deny the petition. • EPA also indicated there were no specific conditions of use identified that would result in systematic, significant airborne exposure that would overlap with terrestrial habitats. However, EPA's Problem Formulation indicated that TRI data show air is a primary medium of environmental release with long-range transport possible via the atmosphere. • Similarly, EPA excluded the disposal pathway, indicating that 1-BP would be assessed and managed under the Resource Conservation and Recovery Act (RCRA). However, 1-BP is not listed as a hazardous waste under RCRA and would only be identified as one if it was disposed of in high enough concentrations to meet the characteristic of "ignitability." • EPA concluded that exposure to 1-BP in drinking water is low based on TRI data from one facility. There is no mention on whether 1-BP has even been looked for in drinking water. EPA cannot equate a lack of evidence of 1-BP's presence in water with evidence of its absence. • EPA should analyze exposure of sediment-dwelling organisms. It is important to note that sediment-dwelling organisms live in or are in contact with the pore water of sediment systems, and therefore, this can be a key route of exposure. Furthermore, higher concentrations of certain contaminants of concern in pore water can increase bioavailability to benthic organisms—meaning, the higher the concentration of the contaminant in the pore water, the more likely it is to cause toxicological effects to act.	rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA. EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment. As stated in the Section 2.3.1.21 of the Risk Evaluation, solid wastes containing 1-BP may be regulated as a hazardous waste under RCRA waste code D001 for ignitable liquids (40 CFR 261.21). 1-BP may also be co-mingled with solvent mixtures that are RCRA regulated substances. These wastes would be either incinerated in a hazardous waste incinerator or disposed to a RCRA Subtitle C hazardous waste landfill. Some amount of 1-BP may be improperly disposed as municipal wastes in RCRA

		Subtitle D landfills, although they are likely to be a small fraction of the overall waste stream. 1-BP migration from RCRA Subtitle C landfills or RCRA Subtitle D municipal landfills will be mitigated by landfill design (double liner, leachate capture for RCRA Subtitle C landfills and single liner for RCRA Subtitle D municipal landfills) and requirements to adsorb liquids onto solid adsorbent and containerize prior to disposal. As stated in the Problem Formulation and in this Risk Evaluation, releases to RCRA Subtitle C and Subtitle D landfills were not included in this Risk Evaluation. Releases injected into UIC Class I hazardous waste wells (subject to joint control under Subtitle C and the Safe Drinking Water Act (SDWA) were also excluded from this Risk Evaluation. With respect to drinking water: As described in Section 4.5 of the Risk Evaluation, EPA considered reasonably available information when characterizing general population exposure to drinking water. In addition to environmental release data reported to the TRI program, there are no data of 1-BP found in U.S. drinking water. 1-BP is slightly soluble in water and volatilizes rapidly from water, such that it is not expected to be present in drinking water supplied from public water systems. In addition, volatilization and biodegradation may attenuate migration of any 1-BP in land-applied sludge that migrate to groundwater. With respect to sediment species: No sediment monitoring data for 1-BP is reasonably available, and physical-chemical characteristics such as a high vapor pressure= 110 mm Hg at 20°C and Henry's law constant of $7.3X10^{-3}$ atm-m^3/mole (see Table 1-1 Physical and Chemical Properties) suggest that 1-BP will quickly volatilize from water and resultingly be present in aquatic environments for a limited duration. Using the physical-chemical characteristics of 1-BP, EPISuite ™ modeling indicates that 1-BP will volatilize from a model river with a half-life on the order of an hour and from a model lake on the order four days. 1-BP in sediment is expected to be in the pore water rather than sorbed to the sediment solids based on a high water solubility (2.4 g/L) and relatively low logKoc (1.6). The Level III Fugacity model in EPA's EPISuite ™ was also used to estimate the steady state

		partitioning of 1-BP between air, water, soil and sediment resulting from releases to water. The model estimated that if 1-BP is continuously released to water, 80% of the mass would remain in water and 19% would transition to air due in part to its water solubility, while only <1% is predicted to transition to aquatic sediment. This output, as well as a qualitative consideration of physical-chemical properties indicates that sediment-dwelling organisms are not expected to be exposed to a greater concentration of 1-BP than organisms in the water-column, so additional risk concerns to these sediment-dwelling organisms are not expected. Furthermore, sediment is not expected to be a source of 1-BP to overlying surface water.
Need additional documentation and input related to Adjustment Factors (AFs)		
SACC	**SACC COMMENTS:** • Include additional documentation and references to justify AFs used and consider using some in silico projections in a corroborative manner in a corroborative manner. (page 38) • Review approach for chronic AF and consider whether AF for fish chronic estimate should be greater than 10. Several Committee members were concerned over the lack of chronic hazard data. One Committee member stated that "if the acute data are uncertain by a factor of 5 and there are no chronic data, the conversion to chronic uncertainty should have more uncertainty than a factor of 2 (5 from acute x 2=10 adjustment factor (AF)). Perhaps the chronic AF should be 50 (5 from acute toxicity x 10 for conversion based on no data) or there is a known or estimated error for 10X acute to chronic toxicity ratios." The same Committee member pointed out that Kienzler et al. (2017) demonstrated that 90-95% of acute to chronic ratios for an individual aquatic fish species are less than or equal to 100. This corresponds to the 10X acute to chronic ratio (ACR) and the 10X AF applied by the Agency, but this does NOT provide any AF to provide interspecies protection. Thus, the AF for fish chronic estimate should be greater than 10. (page 39)	EPA acknowledges that there is uncertainty regarding the use of acute-to-chronic extrapolation to estimate hazards from chronic exposure to 1-BP. In the Final Risk Evaluation document, EPA indicates that an ACR of 10 is consistent with a comparison of the estimated acute and chronic toxicity values produced by (in silico) QSAR modeling (ECOSAR v. 2.0). As explained above, EPA believes that the use of ECOSAR modeling is appropriate for 1-BP. Additional context has been added to Section 3 of the Final Risk Evaluation to understand the protectiveness of an ACR value of 10 in the context of reasonably available literature and information such as ECOSAR modeling. The use of an acute-to-chronic ratio of 10 is consistent with EPA methodology for the screening-level assessment of new chemical substances. EPA is in the process of evaluating the body of reasonably available literature on the subject in order to determine whether to revise standards for application of AF and ACRs for the next 20 high-priority substances undergoing Risk Evaluation. EPA will consider the Keinzler et al., 2017 study in its assessment. Until the body of scientific evidence for assessment factors is evaluated, EPA will continue to use OPPT methodology as cited in the Risk Evaluation and apply an AF of 5 for acute and 10 for chronic aquatic invertebrate data.
Correct errors related to log Koc		

SACC	**SACC COMMENTS:** • Review last two paragraphs on page 188 and correct error by using term **sorption** instead of **absorption**. Committee members generally agreed that 1-BP would be unlikely to maintain significant concentrations in surface waters and associated sediments but the last two paragraphs on page 188 of the DRE should be rewritten to correct errors. . . . . Also see previous comments on sorption to dry soils or biosolids, page 13 under the heading "Environmental Hazards and Risk Characterization." The term **sorption** should be used instead of **absorption** for environmental solids. (page 39) • Review last two paragraphs on page 188 and correct error related to log Koc. Committee members generally agreed that 1-BP would be unlikely to maintain significant concentrations in surface waters and associated sediments but the last two paragraphs on page 188 of the DRE should be rewritten to correct errors. It was stated that no sediment concentrations were expected because of the low Koc value for 1-BP. As mentioned previously, a log Koc of 1.6 still indicates 40 times higher 1-BP concentrations in organic components of the soil at equilibrium. (page 39)	EPA has incorporated the suggested edits into the Final Risk Evaluation.
Add additional release conceptual scenarios		
SACC	**SACC COMMENTS:** • Consider adding conceptual release scenario for indoor air releases from consumer use as degreaser. o Additional conceptual release scenarios which should be considered by the EPA: . . . 2) consumer product releases to indoor air through the use of 1-BP as a degreaser, . . . In all of the described case studies, the Committee acknowledged the lack of release data and struggled with how to frame an appropriate worst-case scenario. (page 41) • Consider adding conceptual release scenario for landfill leachate from insulation disposal. o Additional conceptual release scenarios should be considered by the EPA: 1) insulation occurrence	EPA considered two degreasing conditions of use for consumer exposure (indoor air) aerosol degreaser/cleaner-general and aerosol degreaser/cleaner-electronics. As stated in the Problem Formulation and Section 1.4.2 of the Final Risk Evaluation, 1-BP releases to RCRA Subtitle C and Subtitle D landfills are not included in this risk evaluation. Municipal and hazardous waste landfill design and management controls such as coverings, liners, and leachate collection and treatment may partially or fully mitigate exposures to such releases. No studies to inform the potential for 1-BP to migrate from landfills to the environment were found. 1-BP off-gassing from insulation disposed of in landfills is expected to be in the vapor phase, rather than a liquid or solid/breakdown component

	suggests that disposal is a potential source of environmental exposure through landfill leachate. As mentioned previously, even with a log Kow of 2 which still indicates 100-fold more likelihood of partitioning into organic carbon vs. water and Committee members were not convinced that 1-BP does not partition into organic carbon of sediment (sludge) thus representing a significant data gap; . . . In all of the described case studies, the Committee acknowledged the lack of release data and struggled with how to frame an appropriate worst-case scenario. (page 40-41) • Consider adding conceptual release scenario for transport from subsurface environment to terrestrial organisms via soil vapor. o Additional conceptual release scenarios which should be considered by the EPA: . . . and 3) releases from dry cleaning facilities and industrial sites to the subsurface environment and subsequent transport to terrestrial organisms via soil vapor. . . . In all of the described case studies, the Committee acknowledged the lack of release data and struggled with how to frame an appropriate worst-case scenario. (page 41)	which would enter leachate or groundwater. Vapor phase 1-BP from off-gassing would result in air releases which are addressed by other EPA administered statutes (RCRA and CAA) and therefore not evaluated under TSCA. Additionally, the amount of 1-BP off-gassing is dependent on the age of the insulation board disposed. As stated in Section 2.3.2.4, concentration of 1-BP from off-gassing may initially be high immediately following installation but rapidly decreases (within a few days) to much lower concentrations. Thus, depending on the age of insulation board disposed of, it may contain significantly reduced levels of 1-BP relative to its original concentration upon disposal into a landfill and have a very low off-gassing rate. For 1-BP incorporated into insulation board to enter landfill leachate, it must diffuse through and out of the board into the vapor phase or dissolve into leachate. The rates at which these processes occur is uncertain and dependent on many factors including temperature, age of board, rate of landfill leachate formation and characteristics. Similar factors prohibitively impact EPA's ability to evaluate terrestrial organism exposures from sub-surface environments for which data is unavailable.
Additional SACC Recommendations		
SACC	**SACC COMMENTS:** • Consider alternative approach that would evaluate annual release data: In the absence of 1-BP release data into the environment, the Agency should rework the exposure assessment such that annual releases to air and to water collectively include all 1-BP that is not reported as 1) properly disposed, 2) chemically incorporated in materials, or 3) exported. (page 41) • Consider including a summary of legal thresholds for reporting discharges: The Committee recommended the DRE should include a summary of legal thresholds for reporting 1-BP discharge into air, water, and solid waste streams. (page 40) • Review and provide more detailed description of	EPA does not have reasonably available data to estimate potential environmental releases from improper disposal or from releases that are not otherwise reported to the applicable regulatory program (*e.g.,* TRI); therefore, EPA does not include additional environmental release assessments for these compartments in the Final Risk Evaluation. As described in the 2018 Problem Formulation and the 2019 Draft Risk Evaluation, its p-chem properties suggest that 1-BP will only be present in terrestrial environmental compartments as a transient vapor and is not expected to result in risk concerns to aquatic environments. EPA added additional details to the Final Risk Evaluation Appendix H Estimates of Surface Water Concentration to explain how stormwater releases are estimated as a point-source environmental input from the facility.

	applicability of stormwater data point. The draft risk evaluation documented only a single facility loading value based on a storm water. This release should be described in greater detail to show how stormwater causes a point-source environmental input from a facility. Most Committee members indicated that this single release data point does not likely represent primary discharge pathway to the environment. (page 40)	
	• Consider whether lack of zebrafish study is data gap. Several Committee members stated that a zebrafish study was needed. Given the mammalian toxicity data, reproductive and developmental toxicity with zebrafish is a noticeable data gap. (page 41)	As discussed in the Final Risk Evaluation, the physical chemical properties of 1-BP indicate that chronic exposures to fish are unlikely and therefore reproductive tests are not needed given the aquatic releases expected for 1-BP.1-BP exposure to fish resulted in mortality and sublethal effects. The mortality observed in the acute testing was used in the screening-level risk characterization. The developmental effects were observed following oral exposures to rats include dose-related decreases in live litter size, postnatal survival, and pup body weight, brain weight and skeletal development. While developmental effects may be observed in fish exposure to 1-BP, the zebrafish developmental assay is not considered a critical data gap because the dosing procedure is not adequate to replicate the high oral dosing in the studies with mice and rats. Similarly, making a comparison between inhalation in terrestrial species such as rats and mice and in aquatic organisms such as zebrafish is too uncertain to justify the need for this developmental assay.

Human Health Hazard and Dose-Response Assessments		
Charge Question 5.1: As part of the review, please comment on the choice of these endpoints as PODs for assessing risks in humans associated with acute and chronic inhalation exposures to 1-BP. Specifically, are there other data that EPA could have considered for the hazard identification and dose-response associated with acute inhalation exposures? If so, please provide specific data and references. Are there other data that EPA could have considered for the hazard identification and dose response associated with chronic inhalation exposures? If so, please provide specific data and references. **Charge Question 5.2:** Please comment on the WOE analysis for the choices of non-cancer endpoints for the acute and chronic risk scenarios. Please provide additional data, data interpretation or information that would have informed the WOE analysis and selection of critical studies for the PODs. **Charge Question 5.3:** Please comment on the assumptions, strengths, and weaknesses of this approach including using an inhalation study instead of a limited oral study for route-to-route extrapolation for determining dermal PODs in the non-cancer assessment. **Charge Question 5.4:** Please comment on the nested modeling approach and the selection of endpoints and whether the Draft Risk Evaluation has adequately described the use of this model. **Charge Question 5.5:** EPA concluded in the human health risk assessment that 1-BP carcinogenesis occurs through a mutagenic mode of action (MMOA) based on reasonably available information and the WOE. Please comment whether the cancer hazard assessment has adequately described the WOE regarding the MMOA. **Charge Question 5.6:** Typically, EPA uses the benchmark dose modeling software (BMDS) with a BMR of 10% and the models are restricted to multistage models or the broader suite of dichotomous models in BMDS and a single best model is chosen for the POD. EPA used an alternative approach to calculate the cancer POD versus the standard approach of choosing best fit model and to assess the impact of model uncertainty. Briefly, EPA used two model averaging approaches (frequentist and Bayesian) considering multiple benchmark dose models to calculate the POD at benchmark response (BMR) levels of 0.1% and 10% and for added and extra risk. Please comment on the assumptions, strengths and weaknesses of the model averaging approach for determining the POD in the cancer assessment. **Charge Question 5.7:** In agreement with EPA's long-standing approach, all three tumor types from the NTP study (NTP, 2011) were dose-response modeled with multistage models using the typical constrained model coefficients ≥0 (EPA, 2012). Under the U.S. EPA's 2005 cancer guidelines (U.S. EPA, 2005a), quantitative risk estimates from cancer bioassay data were calculated by modeling the data in the observed range to estimate a BMCL for a BMR of 10% extra risk, which is generally near the low end of the observable range for standard cancer bioassay data. The BMCs and BMCLs are shown for each of the three cancer datasets. The results for a BMR of 0.1% added risk are presented for comparison. Please comment on the assumptions, strengths and weaknesses of the multistage modeling approach for determining the POD in the cancer assessment.		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 5**	**EPA/OPPT Response**
Comments about BMRs used in benchmark dose modeling		
SACC, 31, 47	**SACC COMMENTS:** • The BMR of 10% extra risk which is generally near the low end of the observable range for standard cancer bioassay data was used. As noted by one Committee	In the absence of data indicating a minimal adverse change, EPA does use expert judgement within the boundaries of EPA's Benchmark Dose Guidance and Guidelines for Carcinogen Risk Assessment. According to EPA Guidelines for Carcinogen Risk Assessment, conventional cancer

	member, utilizing Bayesian methods are highly preferred (as recognized by the National Academy of Sciences) as it uses previous knowledge in setting distributions thereby providing more accurate risk predictions. In addition, because parameters are restricted through their prior density, the use of EPA's BMDS 3.0 Bayesian model averaging approach allows for consideration of a large suite of models across many different study designs without typical model "degeneracy" or "overparameterization" concerns of previous model averaging approaches (BMDS 3.0 User Guide). However, it was not clear to the Committee how decisions were made in the risk assessment other than selecting lower values; hence, the decision should be based on accuracy not logic. (page 53)	bioassays can support modeling down to an increased incidence of 1-10%. For non-cancer effects, 10% extra risk is a typical default for quantal data, with 1SD a typical default for continuous data. These defaults can be modified based on supporting data or for more severe (i.e. "frank") effects such as mortality or developmental outcomes.
	• Develop a guidance document with peer-review evaluation and use it with consistency. The selection of 1, 5 and 10% BMR selections appear relatively arbitrary or possibly due to professional judgment. In most cases there are few reasons for their selection with no review of the literature supporting their selection. • Provide a table describing process for deriving BMRs and how related to HECs; also reference those values in documents. In addition, connecting BMR derivations to HECs was difficult and in some cases could not be accomplished by reviewers. A table showing the process and referencing values through the documents to include appendices and supplementary information would improve the clarity of the assessment. (page 46)	EPA acknowledges that current BMD guidance only covers general suggestions and that a formal guidance document specific to BMR selection would be useful to develop in the future. Justifications for BMR selections are provided in Section 3.2.10.1, including references to EPA BMD Modeling Guidance and RfC Guidance. Table 3-2 displays BMCLs based on the selected BMR. Full BMD modeling details are provided in: *Supplemental File: Information on Human Health Benchmark Dose Modeling.*
	PUBLIC COMMENTS: • It is unclear how and why a different BMD (Benchmark Dose) was deemed to be required in the draft risk assessment. The use of "uncertainty factors" to lower the results of a BMD analysis in and of itself is a topic which the Peer Review Committee should discuss. There is disagreement regarding the use of the non-standard 0.1% added risk rather than the standard 10% BMR	The commenter appears to be referring to BMR selection. BMR selection is explained in Section 3.2.10.1 for noncancer data. The 0.1% BMR refers to the cancer dose-response modeling. As stated in the Risk Evaluation (now relabeled as Section 3.2.10.2.1), "two options for BMR (0.1% and 19%) added or extra risk were both modeled for comparison with EPA's 2005 cancer guidelines and comparison with the 2016 Draft Risk Assessment and the 2016 NIOSH draft criteria document." 0.1% added cancer risk is consistent with the 2016

	(Benchmark Response) modeled using the BMDS (Benchmark Dose Software). There should be clear scientific rationale for the change. It seems that EPA is arbitrarily lowering the effect level to obtain a more stringent POD (Point of Departure). • The selection of different BMRs for different endpoints should be carefully reviewed. There is a lack of transparency on the Agency's rationale for focusing on certain endpoints that are deems "relevant, sensitive, and found in multiple studies." Fertility index, rather than the number of resorbed Corpora Lutea, should be an endpoint since it is directly relevant to humans. Also, reduction in body weight gain is a commonly cited endpoint that has been retracted by the study's author in an errata (Huntingdon Laboratories developmental study, 1999).	NIOSH draft criteria document. The calculated IUR are almost identical when using a BMR of either 10% or 0.1% ER (both 1 x 10^{-6} for 24hr/day exposure), so the BMR selection does not impact the POD derivation for the linear dose-response analysis. Justifications for BMR selections are provided in Section 3.2.10.1, including references to EPA BMD Modeling Guidance and RfC Guidance. Fertility index is an endpoint with a POD presented in Table 3-2. Pup body weight gain was not selected as a developmental POD to be used for risk estimation.
Comments about dermal risk assessments		
SACC	**SACC COMMENTS:** • Consider contribution of dermal exposure to systemic exposures in workplace. One Committee member agreed that dermal exposure may be an important contributor to systemic exposures to Volatile Organic Compounds (VOCs) in the workplace, and that an estimate of dermal exposure to 1-BP should be included. (page 47) • Ensure to estimate cumulative exposures, which involves both dermal and inhalation contact with 1-BP. It was pointed out by several Committee members that dermal exposure to 1-BP would most likely correspond with simultaneous inhalation exposure. • Include an explanation for the estimate of a single exposure event. It is not clear why the underlying EPA dermal model assumes one exposure event per day, which likely underestimates exposure as workers come into contact with 1-BP several times during the workday. Based on these uncertainties, the EPA has expressed only a medium level of confidence in the assessed baseline exposure. • Provide details for and validity of approach for deriving assumptions in calculating a Dermal-HED from an	Additional explanation regarding cumulative risk assessment is provided in Section 4.4.2 of the Risk Evaluation. There is low confidence in the result of aggregating the dermal and inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk. Given all the limitations that exist with the data, EPA's approach is the best available approach. As described previously under Charge Questions 2 and 3, the Final Risk Evaluation provides additional information on the assumptions associated with EPA's dermal exposure models, including basis for the exposure event. Oral studies were insufficient for dose-response analysis, and therefore route-to-route extrapolation from inhalation studies was necessary for obtaining dermal PODs. The process for extrapolation is provided in Section 3.2.10.4. Extrapolation

	Inhalation-HEC. Details for how the assumptions were derived in calculating a Dermal-HED from an Inhalation-HEC need to be provided. The validity in these assumptions need to also be provided. (page 44)	uses estimated average breathing rate for workers (1.25m^3/hr, from the ChemSTEER engineering model) over 6hr, with 80kg as body weight (from the 2011 Exposure Factors Handbook).
31, 47	**PUBLIC COMMENTS:** • EPA's decision to rely on inhalation-to-dermal extrapolation contributes substantial uncertainty to its risk calculations. EPA should incorporate pharmacokinetic information from a 2005 rodent study that evaluated the dermal contribution to overall internal dose during a whole-body inhalation chamber exposure period.	The inhalation to dermal extrapolation is used in estimating risks from exposures to liquid 1-BP by direct contact with skin. EPA believes this method is best available science despite the uncertainties described in the Risk Evaluation. EPA's choice to not model the exposure to 1-BP of vapor through skin is based on the toxicokinetic studies (Garner et al 2014 and 2015) that evaluated the adsorption of 1-BP to fur and skin and the absorption of 1-BP from the air through skin and generally found a small amount of 1-BP absorbed by skin.
Concerns about integration of evidence for Mode of Action (MOA)		
SACC	**SACC COMMENTS:** • Conduct original data quality review for all key studies that impact MOA. For all key studies that impact the MOA determination (which would be many of the genotoxicity studies), the article containing the original data should be evaluated for quality and reviewed. (page 51) • Consider alternative approach that 1-BP acts through non-mutagenic mode of action and explore use of non-linear threshold model. Committee members had mixed opinions as to whether the EPA should conclude that 1-BP acts through a MMOA. . . . Another Committee member emphasized that the multiple negative in vitro and in vivo tests should be given more weight than the limited number of positive in vitro tests, and that 1-BP should be concluded to act through a non-mutagenic mode of action. Consequently, this Committee member believed that the use of a non-linear threshold model to estimate risks in the low dose region should be thoroughly explored and discussed. (pages 50-51) • Consider alternative approach that sufficient evidence	In the Final Risk Evaluation, EPA has included data quality review and data extraction of all reasonably available genotoxicity studies identified in the relevant literature database. The three additional studies suggested by the SACC (Nepal et al., 2019; Stelljes et al., 2019; Thapa et al., 2016) were also systematically reviewed and added to the Risk Evaluation. All other studies suggested were previously included in the Risk Evaluation. In the Final Risk Evaluation EPA determined that the evidence for a mutagenic mode-of-action for 1-BP carcinogenicity is suggestive but inconclusive, based on a re-evaluation of the available genotoxicity and mode-of-action data. The linear dose-response assessment from the previous draft of the Risk Evaluation was retained since EPA further determined that no other specific mode-of-action hypothesis has been proposed in enough detail or studied adequately to permit an evaluation. While other potential cancer modes-of-action are mentioned in general terms in the Risk Evaluation, no corresponding specific proposals are elucidated or evaluated. Per EPA policy, a linear dose-response model is

	exists to conclude that 1-BP acts through a MMOA. Committee members had mixed opinions as to whether the EPA should conclude that 1-BP acts through a MMOA. . . . Other Committee members believed that the EPA should be health-protective, and while acknowledging the uncertainty, indicated that the evidence was sufficient to conclude that 1-BP acts through a MMOA. Given this conclusion, one Committee member indicated that EPA would be justified to estimate cancer risk from acute exposures as mentioned in the public comments. (page 50) • Consider alternative approach that would conclude the MOA for 1-BP is unknown. Committee members had mixed opinions as to whether the EPA should conclude that 1-BP acts through a MMOA. Some Committee members believed that the negative in vivo results should be given priority over the in vitro screening assays, and as a result, recommended that the EPA conclude that the MOA for 1-BP is unknown. This would be more consistent with accepted approaches such as the International Programme on Chemical Safety mutagenicity test scheme (see Eastmond et al., 2009). (page 50) • Consider recent carcinogenicity data that support non-mutagenic threshold MOA, specifically Steljas (2019) which supports a non-mutagenic threshold mechanism of action for carcinogenicity. (page 45) • Review and, if applicable, include new studies on genotoxicity of 1-BP. Several new studies on the genotoxicity of 1-BP have recently been published and are listed below. These were not captured in the literature search and are clearly relevant to genotoxicity and mode of action evaluations. If these pass the EPA's quality review, they should be included in the report. ○ Thapa P, Kim E-K, Nepal, MR, Jeong KS, Noh K, Lee S, Jeong HG, Lee H-H, Jeong TC, Lee E-S (2016) Identification of a N 7-guanine adduct of 1-BP in calf thymus DNA by mass spectrometry, Molecular	applied by default for assessment of carcinogenicity risk for chemicals for which mode-of-action has not been conclusively demonstrated ((U.S. EPA, 2005b) Cancer Guidelines).

	and Cellular Toxicology 12:7-14. ○ Nepal MR, Noh K, Shah S, Bist G, Lee ES, Jeong TC. (2019) Identification of DNA and glutathione adducts in male Sprague-Dawley rats exposed to 1-BP. J Toxicol Environ Health A. 82(8):502-513. ○ Stelljes M, Young R, Weinberg J. (2019) 28-Day somatic gene mutation study of 1-BP in female Big Blue(®) B6C3F1 mice via whole-body inhalation: Support for a carcinogenic threshold. Regul Toxicol Pharmacol. 104:1-7. [This appears to be the same study described as Weinberg (2016) in the document.] (page 51)	
25, 38	**PUBLIC COMMENTS:** • The draft risk evaluation for 1-BP does not fully evaluate, discuss, or weigh the scientific evidence of the potential alternative interpretation of the data and analyses using a cancer MOA approach. EPA should re-evaluate the MOA for 1-BP and consider an alternative MOA (non-mutagenic, threshold MOA for tumor formation)	
31	**PUBLIC COMMENTS:** • Comment 31 disagrees that MMOA (Mutagenic Mode of Action) is an appropriate assumption upon which to base cancer models. Even if immunosuppression is a possible other mechanism, it is not and does not support a MMOA so the model used to estimate cancer potency is still inappropriate even if some other MOA is operating. Weight of the evidence does not support a MMOA for 1-BP carcinogenesis. Evidence of a non-mutagenic mode of action (Stelljes et al. (2019)) should be referenced and included in the final report. Cancer potency methods and MOA conclusions should be updated appropriately.	
47	**PUBLIC COMMENTS:** • A number of concerns have been identified in the study suggesting 1-BP acts through a non-mutagenic/non-genotoxic MOA (Stelljes et al., 2019). These concerns indicate its utility in understanding the MOA of 1-BP may be limited and/or its results misleading. The study was entirely funded by EnviroTech International, has	In response to the later comments, all studies, including

	been the industry-leading provider of solvents, including 1-BP, for over twenty years. • The use of the linear extrapolation is the only appropriate option for cancer dose-response modeling for 1-BP. Regardless of the postulated mechanism, it is essential that EPA describe the cancer classification of 1-BP as more definitive than as currently stated in the draft risk evaluation.	industry led studies, are evaluated using the same metrics to apply a non-biased evaluation of each study independent of any other study.
Important epidemiologic data were neglected and the decision process is unclear		
SACC, 26, 36, 54, 49, 47	**SACC COMMENTS:** • Provide greater weight to Ichihara et al. (2000) neurotoxicology study for WOE. Ichihara et al. (2000) is a more appropriate study than Honma et al. (2003) for the reasons outlined in response to charge question 5.1 and should be given greater weight. However, Honma et al. found effects at a lower dose, therefore, from a protection perspective, Honma et al. might still be used to provide better protection for occupational workers and consumers from 1-BP exposure. Inclusion of information on scoring of studies would be helpful in this context. (page 45) • Add Ichihara et al. (2000a) study to Table 3-1 under the heading for Nervous System as it relevant for neurotoxicity. (page 45) • Add second table indicating WOE analysis for each endpoint within endpoints chosen. This would be helpful in supporting the choice of specific studies and specific endpoints for POD selection. (page 46) **PUBLIC COMMENTS:** • Human studies should not be dismissed. The decision to dismiss the human epidemiologic evidence has direct implications for assessing population risks, as it is likely that use of human epidemiologic data from the study database would have resulted in identification of a POD considerably lower than that derived by EPA using Honma et al. (2003). EPA does not provide a convincing argument for outright exclusion of three human epidemiological studies on the health effects of 1-BP –	EPA believes the (Honma et al., 2003) study better captures exposure concentrations of interest for the neurotoxicity effects relevant to 1-BP. Compared to the (Ichihara et al., 2000) study, (Honma et al., 2003) tested lower concentrations down to 10 ppm and this was a NOAEC. EPA corrected references in Table 3-2. Ichihara et al (2000a) was previously included in referenced table (now Table 3-2), however it was mistakenly referred to as WIL Research, 2001. It is now included as the second row from the bottom. EPA did not add the additional metabolites to Figure 3.3 but did add a citation to the IARC monograph for other possible metabolites. The human database was not considered adequate for dose-response analysis, however EPA agrees that it supports the

	Ichihara et al. (2014), Li et al. (2010) and Toraason et al. (2006). Any exclusion of the human epidemiological evidence in the 1-BP risk evaluation must be clearly justified, including a presentation of the impacts of this exclusion on PODs and associated measures of margins of exposure (MOE), and its public health implications. • For the weight of evidence for 1-BP's neurotoxicity, EPA uses only rat studies on 1-BP to calculate an MOE and does not rely on human studies that showed neurotoxic effects at levels 10X below concentrations producing these effects in rats. In fact, multiple human studies are available that show consistent evidence of neurotoxicity in exposed workers at low concentrations. • EPA must consider the broader availability of evidence from human studies of 1-BP, including a more holistic consideration of the combined database of case reports and occupational epidemiologic studies. In addition, EPA provides neither an explanation nor empirical support for its revisions to the systematic review data quality criteria for epidemiological studies, and certain revisions make it more difficult for epidemiological studies to be scored overall as high quality. Given the concerns related to the appropriateness of the OPPT tool for epidemiologic studies, the agency needs to consider use of other study evaluation tools that are available and are more appropriate for assessing the quality of observational epidemiologic studies.	weight of evidence for neurotoxicity and the selection of the lower POD from Honma et al over Ichihara et al. EPA used a 10x uncertainty factor (UF) for animal to human extrapolation, so a 10x difference between effect levels is consistent with EPA's POD selection. The human evidence contributes to the strong WOE for the neurotoxicity domain. EPA did not identify any epidemiological studies based on numerous study weaknesses identified during data evaluation of systematic review that were adequate for dose-response analysis (See Appendix J). The epidemiological criteria for study evaluation are also included in Appendix J. EPA/OPPT's quality evaluation method was developed following identification and review of various published qualitative and quantitative scoring systems to inform our own fit-for-purpose tool. The development process involved reviewing various evaluation tools/frameworks (*e.g.*, OHAT Risk of Bias tool, CRED, etc.; see Appendix A of the *Application of Systematic Review in TSCA Risk Evaluations* document and references therein), as well as soliciting input from scientists based on their expert knowledge about evaluating various data/information sources specifically for risk assessment purposes. The epidemiologic criteria were revised to more stringently distinguish between High, Medium and Low studies. After additional piloting of the criteria, EPA found that the initial iteration of the epidemiologic data quality criteria (as published in the *Application of Systematic Review in TSCA Risk Evaluations*) was inadvertently skewing quality scores toward the tail ends of the scoring spectrum (High and Unacceptable). In order to have the criteria represent a more accurate depiction of the quality levels in the epidemiologic literature, the criteria were revised using two methods.

		The first method was to make the unacceptable metrics less stringent. This was accomplished by either rewording the metrics to allow for more professional judgement in the interpretation of the unacceptable criterion, or in some cases, completely removing the unacceptable bin from metrics that EPA determined were not influential enough to completely disqualify a study from consideration (mostly metrics in the Analysis and Biomonitoring domain). EPA found that these criteria changes greatly reduced the type one error in the Unacceptable scoring. Acceptable studies were not inaccurately classified as Unacceptable. The second method was to reduce the number of studies that received an overall High rating. Most overall scores in EPA's initial evaluations during piloting tended to be High. Therefore, EPA strived to revise the criteria to provide more degradation in the scoring to more accurately and objectively distinguish studies of the highest quality from medium and low-quality studies. To do this, EPA removed the High criterion from some metrics, particularly in dichotomous metrics (High/Low or High/Unacceptable) that were primarily being binned as High by reviewers across the majority of the studies. These dichotomous metrics were contributing to the overall quality scores being skewed towards High. To address this, EPA shifted some of the dichotomous metrics such that the highest metric score possible (for all studies) is a Medium. The change led to the dichotomous metrics having less significant impact to the numerical scoring and the overall quality rating for each study. With the aforementioned changes to the criteria, EPA observed fewer studies with Unacceptable ratings and more studies shifting from High to Medium, with only the highest quality studies receiving a High overall rating. Out of the ~200 relevant epidemiologic studies and cohorts evaluated for data quality for the first 10 TSCA chemicals, the majority (~80%)

		still scored as High or Medium. The remaining ~20% of studies scored Low or Unacceptable. EPA is confident that no studies of acceptable quality were inappropriately assigned as Unacceptable. EPA is also confident that the revised criteria bins the quality levels of these epidemiological studies more appropriately than the previous iteration. Additional refinements to the epidemiologic data evaluation criteria are likely to occur as EPA's validation and process improvement efforts continue.
Interpretation of mouse lung tumor data		
29, 37	**PUBLIC COMMENTS:** • One of the major problems in NTP 2-year rodent bioassays is a high false positive rate (*i.e.,* there is poor correlation with human cancer risk). Mouse lung tumors represent a level of sensitivity to chemical carcinogenesis that is much higher than would be expected in humans. In addition, mouse lung tumors induced via chronic inhalation of certain chemicals are not relevant to the risk of developing human lung cancer. The National Toxicology Program (NTP) 2-year inhalation study on 1-BP suffers from interpretability issues due to problems in extrapolating bronchioloalveolar lung tumors in mice to pulmonary adenocarcinomas in humans.	EPA considers animal tumor findings relevant to evaluations of human risk, in the absence of convincing data to the contrary. This includes mouse lung tumors for 1-BP. The available mode-of-action data for 1-BP are suggestive (although not conclusive) of a mutagenic mode-of-action, which would be presumed potentially operative in tissues throughout the body and relevant to humans. There are no data indicating a different mode-of-action for 1-BP mouse lung tumors specifically or the relevance of that mode-of-action to humans. The relevance to human health of mouse lung tumors observed in assays for naphthalene and related chemicals remains an unsettled question, but there is no reason to suspect, nor evidence to support, a mode-of-action similar to those chemicals for 1-BP. The MOE is a standard risk assessment approach. EPA applies an MOE approach because it allows for the presentation of a range of risk estimates and does not create a "bright line." EPA has inserted a definition of the benchmark MOE in the "human health risk estimation approach." EPA has added information to Appendix J.6 indicating "the data suggest that 1-BP may be a direct-acting mutagen since similar responses were observed both with and without metabolic activation."
47	**PUBLIC COMMENTS:** • Also, EPA should implement the recommendations of the NAS and develop a unified approach to presenting dose-specific population risks for both cancer and noncancer endpoints. • Regarding Albemarle's point that the mouse model doesn't represent humans, EPA must consider the potential for 1-BP to be a direct-acting mutagen, which is neither a species-specific nor related to CYP2E1 levels. Furthermore, individuals with increased CYP2E1 expression (*e.g.,* alcoholics, diabetics) would have increased production of toxic metabolites, suggesting that a mouse model with increased production of toxic metabolites would still be relevant to consider in order to meet TSCA's mandate that EPA evaluate the risks of	

	chemicals to potentially exposed or susceptible subpopulations.	
Repair errors and typos in the report		
SACC	**SACC COMMENTS:** • Correct apparent editing error on page 166 of the DRE, which states, "The POD for increased post-implantation loss was a BMCL of 24 ppm." This apparent editing error requires correction. (page 48) • Correct errors in appendix references on page 153 and 155 of the DRE. Page 153 refers incorrectly to Appendix H; should be Appendix I. The same correction applies to page 155 in the paragraph describing Developmental Toxicity. (page 45) • Correct typographical errors on page 161 line 2 of the DRE: "161imilar161hological." (page 45)	EPA has corrected these editorial errors in the Final Risk Evaluation.
Recommendations to improve the modeling approach		
SACC	**SACC COMMENTS:** • Human Equivalent Concentrations (HECs) were derived, according to U.S.EPA (1994), by simply calculating a dosimetric adjustment factor (DAF) based only on the ratio between the animal and the human blood: air PC. These values were 11.7 and 7.08, respectively. Although the rat PC was 1.7X higher, a default ratio of 1 was applied. As a Committee member pointed out, the primary determinants of systemic absorption of inhaled VOCs are alveolar ventilation rate, cardiac output (*e.g.*, pulmonary blood flow rate), and 1-BP metabolic rate. All of these are substantially higher in mice than rats, and higher in rats than in humans. Thus, rodents will receive a significantly higher internal dose of 1-BP than humans upon inhalation of the same vapor concentration for the same period of time. PBPK models must take these physiological interspecies differences into account. (page 54) • There was concern that the assumption of a 1:1 interspecies extrapolation of systemic dose for inhalation exposures is not scientifically valid. This concern must be addressed.	The only PBPK model available for 1-BP is for inhalation exposure in the rat (Garner et al., 2015). Extrapolation across species using this model is precluded by lack of data to inform a model of another species. In the absence of a suitable PBPK model, the EPA (1994) Methodology for Derivation of Inhalation Reference Concentrations describes dosimetric equations to calculate Human Equivalent Concentrations (HECs) from animal data. For gases, such as 1-BP, with toxic effects outside of the respiratory tract, the chemical's blood:air partition coefficient is the key quantity, specifically the ratio of the value in the test species to the value in humans. Further, EPA (1994) made the policy decision that a dosimetric adjustment factor (DAF) of 1 is used for chemicals like 1-BP where the value is larger in the test species than in humans, in order to be protective of human health, ensuring that a POD (HEC) derived in this way is never higher than the corresponding POD from an animal study. EPA did not assume a 1:1 value of animal doses to human. The derivation of a Human Equivalent Concentration/Dose is presented in Section 3.2.10.2 and involves adjustment for exposure duration and allometric scaling.

	• Consider utilizing Bayesian methods in setting distributions for more accurate risk predictions. It is not clear how decisions are made in the risk assessment when it relates to selecting lower values. • Ensure crucial data required to assess multi-stage modeling is excluded in the risk assessment so that relevant supplemental files are easily assessible. • Regarding page 176 – were Bayesian model approaches used for non-cancer studies? If not, please clarify which model approach was used and why.	EPA used reasonably available information for the Risk Evaluation of 1-BP. Due to time and resource constraints EPA cannot implement a Bayesian framework comprehensively for this risk evaluation; however, EPA will consider incorporating more probabilistic modeling into future risk evaluations under TSCA.
	• Remove the high dose data for implantation loss (which trended lower) leaving three data points inclusive of a control, all of which had relatively high variation.	Section 2.1.2 of the *Supplemental Information on Human Health Benchmark Dose Modeling* shows results both with and without the high dose. In addition, a sentence was added to Section 3.2.10.1 of the Risk Evaluation to explain that the data without the high dose were chosen for the POD.
	• The draft risk assessment should describe what, if anything, is being done to increase risk assessment of cancer risk for short-term human exposure.	The Risk Evaluation for 1-BP does not estimate extra cancer risks for acute exposures because the relationship between a single short-term exposure to 1-BP and the induction of cancer in humans has not been established in the current scientific literature. The 2005 Carcinogen Risk Assessment Guidance states: "Use of short-term data to infer chronic, lifetime exposures should be done with caution. Use of short-term data to estimate long-term exposures has the tendency to underestimate the number of people exposed while overestimating the exposure levels experienced by those in the upper end (*i.e.*, above the 90^{th} percentile) of the exposure distribution." Additionally, based on a linear dose-response assuming equivalent contribution of risk over time, cancer risk is evaluated based on lifetime average daily concentration/dose. As explained in the Risk Evaluation, Section 3.2.8.2.1, according to the NRC (2001), "There are no adopted state or federal regulatory methodologies for deriving short-term exposure standards for workplace or ambient air based on carcinogenic risk, because nearly all carcinogenicity studies in animals and retrospective epidemiologic studies have entailed

		high-dose, long-term exposures. As a result, there is uncertainty regarding the extrapolation from continuous lifetime studies in animals to the case of once-in-a-lifetime human exposures. This is particularly problematical, because the specific biologic mechanisms at the molecular, cellular, and tissue levels leading to cancer are often exceedingly diverse, complex, or not known. It is also possible that the mechanisms of injury of brief, high-dose exposures will often differ from those following long-term exposures. To date, U.S. federal regulatory agencies have not established regulatory standards based on, or applicable to, less than lifetime exposures to carcinogenic substances."
SACC	• The *Draft Risk Evaluation for 1-Bromopropane: Supplemental Information on Human Health Benchmark Dose Modeling* states "The application of nested dichotomous models to these data was possible because the incidence data for post-implantation loss were available for every litter, and preferable because they can account for intra-litter correlation and litter-specific covariates." The rationale for using a nested modeling approach to account for litter effect was not clear and must be clarified.	The rationale for use of nested models (*i.e.*, to account for litter effects) in dose-response modeling of developmental toxicity data was added to the Risk Evaluation.
SACC	• Details concerning the rationale for the multistage approach were not present in the 2019 draft risk assessment and should be added.	The rationale for use of the multistage model for cancer dose-response modeling was added to the Risk Evaluation.
SACC	• Qualify study data robustness along with other study quality criteria in determining value of data for HEC derivation and risk assessment. Control groups consist of background reductions in implantation loss.	EPA finds it impractical to score during quality evaluation the effectiveness of the study in demonstrating an effect, if that is what is being suggested, because that would vary with measurement endpoint and a given study might present data for dozens of measurement endpoints.
SACC	• It was unclear to the Committee as to why the EPA used a standard Uncertainty Factor (UF) for animal-to-human extrapolation when they already applied a dosimetric adjustment factor (DAF) in addition to other allometric adjustments to account for species differences due to kinetics. • When kinetics is considered, the appropriate UF to use is	This issue is addressed in Section 4.2.1 of the Draft Risk Evaluation. A full interspecies UF_A of 10 was applied, including factors of 3 each for toxicokinetics and toxicodynamics, despite application of the EPA (1994) dosimetric equations (which would typically eliminate need for the 3-fold factor for toxicokinetics) because 1-BP is irritating to the respiratory tract. Rodents exhibit physiological

	3; however, this is with a PBPK model. However, there is information that rodents would be more sensitive, so please scientifically support the use of an UF from animal to human.	responses (such as reflex bradypnea) to irritants that differ from human responses and may alter uptake (e.g. decreasing uptake due to hypo-ventilation). Cross-references in Sections 4.2.1 and 4.3.4.2 were added to Tables 3-2 and 3-8, which list the UFs and explanations for UFs used.
SACC	• The importance of reduction in post-implantation sites is unclear as it relates to humans (as typically humans have one birth at a time, not several). Further, if the selection of lower BMR levels are intended to be more protective of more important endpoints, it would be advisable to conduct a sensitivity analysis of this procedure as there are other means for protecting vulnerable subpopulations (*e.g.*, intraspecies UFs).	Per EPA (U.S., 1998) Guidelines for Reproductive Toxicity Risk Assessment, understanding the mechanisms controlling reproduction supports the use of data from experimental animal studies to estimate the risk of reproductive effects in humans. An agent that produces an adverse reproductive effect in experimental animals is assumed to pose a potential threat to humans. For developmental outcomes, the specific effects in humans are not necessarily the same as those seen in the experimental species, due to species-specific differences in timing of exposure relative to critical periods of development, pharmacokinetics (including metabolism), developmental patterns, placentation, or modes of action.
Comments about mutagenicity and carcinogenicity		
SACC	**SACC COMMENTS:** • Clarify reference for statement about metabolic activation in Section 3.2.8.3. In Section 3.2.8.3, it states that 1-BP "induced DNA damage and repair in human cells in culture in the presence of metabolic activation." A reference supporting this could not be found. It appears to be based on Toraason et al. (2006), which looked only at DNA breakage (not repair) and did not use metabolic activation. (page 52) • Consider including additional genotoxic metabolites in metabolic pathway figures. Important identified or putative genotoxic metabolites (glycidol and propylene oxide) are not shown in the metabolic pathway figures. The Committee recommended that a figure similar to Figure 4-1 in the IARC monograph on 1-BP which includes these metabolites be included. However, if and when formed, their role in 1-BP carcinogenesis is uncertain as they would appear to be two of many metabolites, and 1-BP itself is directly converted into an electrophilic species. (pages 52-53)	The detailed reporting of genotoxicity results was removed from Section 3.2.8.6 (previously 3.2.8.3), eliminating the inaccurate text noted in the comment. EPA added a citation to the IARC monograph for other possible metabolites; however, did not add the additional metabolites to Figure 3.3.

	• Consider mentioning scientific viewpoint that N7-guanine adduct is more a biomarker of exposure. It should be noted that for many years, there has been a discussion about the significance of the N7-guanine adduct with some proposing that it is more a biomarker of exposure rather than one of effect. These adducts, particularly small adducts, are considered by some to be relatively short-lived and not directly associated with mutagenesis (Boysen et al., 2009). This should be at least mentioned in the document. (page 52) • Consider open-system studies for Salmonella mutation data. With regards to the Salmonella mutation data, the open-system studies should be examined in at least some detail as they may provide useful information. (page 52) • Consider suggested sources that list genotoxicity studies to help identify relevant studies. Lists of genotoxicity studies can often be found in monographs or databases produced by the ATSDR, International Agency for Research on Cancer (IARC) and ECHA. These should be examined early in the evaluation to ensure that all relevant studies had been identified. For example, in examining the ECHA database, a number of studies appeared to be missing from the EPA document. Six Ames test studies are identified in the ECHA database but only two are described in detail in the EPA report and two more are only briefly mentioned. (page 52) • Improve clarity and accuracy of Table Apx I-4. Table Apx I-4. Genotoxicity of 1-BP *in vitro* needs to be updated and corrected as well. There were two separate Ames test studies reported by the NTP (2011a). These should be presented individually in the table. (page 52). A table summarizing the *in vivo* genotoxicity studies should also be included. • Include more discussion about negative genetic toxicology studies in Section 3.2.7.2. More discussion of the negative genetic toxicology studies is needed in Section 3.2.7.2. One Committee member believed that all studies need to be discussed and if some were not used,	It is now noted in the Risk Evaluation with regard to the findings of the Thapa (2016) and Nepal (2019) studies that the observed N7-guanine adducts are not known to result in mutations. The discussion of bacterial mutagenicity tests conducted using open systems was enhanced in appropriate sections of the Risk Evaluation. The first sentence of Section 3.2.7.2 was re-written so as not to exclude the open studies. With the Final Risk Evaluation, EPA has included data quality review and data extraction of all reasonably available genotoxicity studies identified in the relevant literature database. EPA has added additional key genotoxicity studies to the table (now Table Apx_J-4) which includes in vitro, in vivo, and epidemiological data. Data evaluation scores are also provided in the table for each study. The discussion of genotoxicity in Section 3.2.7.2 and elsewhere in the text was modified to present a balanced picture of the findings contained in the database, including both positive and negative results.

	the reason why should be provided. Currently the focus is primarily on the positive studies with rigorous critiques of several key negative studies. (page 52) • Include summary table for *in vivo* genotoxicity studies. A table summarizing the *in vivo* genotoxicity studies should also be included. (page 52)	With the Final Risk Evaluation, EPA has included data quality review of all reasonably available genotoxicity studies identified in the relevant literature database.
Additional SACC Recommendations		
SACC	• Clarify reference for source of *in vitro* data using calf thymus DNA. In Section 1.5.6 (and elsewhere) it indicates that "1-BP has been shown to bind covalently to DNA to form N7-guanine adducts in an *in vitro* system using calf thymus DNA." The reference given is Lee et al. (2007). The data supporting the statement is not in that article. (page 51). A similar statement is made in the discussion which refers to a Lee et al. (2003) abstract in Toxicological Sciences. It seems unlikely that the original source was evaluated and if so, it should have been cited directly. (page 50-51) • Consider two recent publications (Thapa et al., 2016; Nepal et al., 2019) as replacements for Lee et al. (2007). (page 52)	The Thapa (2016) and Nepal (2019)studies have been added to the Risk Evaluation. The Lee et al. (2007) study is no longer cited for the N7-guanine adduct information that was later published in Thapa (2016) .
SACC	**SACC COMMENTS:** • Clarify focus of Section 3.2.7.2 through adding introductory sentence to indicate that the focus is on bacterial assays using closed systems to test a volatile compound. (page 52)	Information on mammalian cell in vitro and in vivo data has been added to the section. It is now more representative of the full genotoxicity database for 1-BP.
SACC	• Clarify that if there are no statistical differences, the means are not different. For example, on page 155, "Animal studies suggest that the reproductive system is a target of concern for 1-BP exposure. A two-generation reproduction inhalation (via whole-body exposure) study in rats reported adverse effects on male and female reproductive parameters (WIL Research, 2001). Most of these effects exhibited a dose-response beginning at 250 ppm, with statistical significance observed at 500 ppm." The difference between means was not statistical at 250 ppm.	A dose-response can be observed in the absence of statistical significance. EPA's description does not state that there is statistical significance at the lower dose, only that a dose-response relationship is observed between 250 and 500 ppm, with statistical significance achieved at the higher dose.

SACC	• Clarify source of information on pre-incubation periods (page 394 of DRE). It is also not apparent where the information on the 1-BP concentrations at the beginning and end of the pre-incubation periods (page 394) came from in describing the Bioreliance (2015) study. This information could not be found in the study itself. (page 52)	The commenter seems to be referring to the passage on p. 394 of the Draft Risk Evaluation: "However, despite the use of screw-capped tubes to reduce 1-BP loss via volatilization during preincubation with the bacterial test strains, analytical concentrations of 1-BP in preincubation tubes during the BioReliance study (2015) confirmatory assays were far below target, with 4-37% of target concentrations at the beginning of the preincubation period and 2-5% of target concentrations by the end of the preincubation period. At the highest target exposure concentration of 5000 µg/plate, the measured concentrations during preincubation correspond to approximately 100-450 µg/plate (2-9% of the target concentration) in the BioReliance study (2015) and no evidence of mutagenicity was seen at this or lower concentrations." The concentrations of 1-BP at the beginning and end of the pre-incubation period are provided in Tables 13 and 17 of Appendix IV (pages 69 and 71, respectively) of BioReliance (2015). The pre-incubation period was 90 minutes (p. 17 of BioReliance, 2015). Samples for chemical analysis were taken from the high dose and low dose pre-incubation tubes (pp. 10-11 of BioReliance, 2015). The results of analysis are presented in Tables 13 and 17 of Appendix IV of BioReliance (2015) for the first and second confirmatory assays, respectively.
	• Consider using a secondary source if original study unavailable. The original citation should be listed followed by "as cited in" and then the secondary source should be listed. (page 51)	EPA does rely on authoritative secondary sources (i.e. IRIS, ATSDR) when relevant.
	• Describe the basis for Human Equivalent Concentrations (HEC, developmental) and compare it with human experience (neurological) OR compare it in the text.	The process for deriving HEC values from toxicity studies is provided in Section 3.2.10.2.
	• Provide consistency in reporting unpublished studies. In some cases, the author or study director is listed. In others, the test laboratory or the sponsoring company is listed. When available, the authors of each study should be reported, not simply the test laboratory, name of the sponsoring organization, or who provided the study to the	EPA practice for the Risk Evaluations has been to report the contract laboratory as the study author for unpublished, contracted studies.

	EPA. Standard formatting for unpublished studies should be available from other offices at the EPA (OPPT) or other sources such as the Joint Meetings on Pesticide Residues (JMPR). (page 51)	
	• Provide rationale for how decreased live litter size is used to characterize chronic exposure. Both post-implantation loss and decreased live litter size are being used for both acute and chronic exposures. The argument was already made by the EPA that the live litter size decrease was from a short-term exposure. The rationale for how it is now being used to characterize chronic exposure needs to be explained. (page 44)	Developmental effects can occur following either acute or chronic exposure. Developmental toxicity studies cover subchronic to chronic durations, so the applicability of developmental effects to chronic exposure is inherent. EPA did not apply any additional subchronic-to-chronic UF to developmental studies for estimation of chronic risk.
SACC	• Regarding page 247 – "Neurotoxicity produced by 1-BP are based on rodent and human literature, with considerable similarities in both qualitative and quantitative outcomes." Please provide that comparison in this section referencing Table Apx I-1, pages 346-347.	A reference to Appendix J.2 and J.3 (details on the animal and human neurotoxicity literature) has been added to the uncertainties discussion where that statement appears.
	• Regarding Table 4-26, page 205 – It is not clear why high intensity use of 1-BP results in a high WOE than low intensity use for coin cleaner, AC flush and overall. Was this an error?	EPA appreciates the commenter pointing out this mistake. The table has been corrected for coin cleaner and AC flush. The "overall" row has been removed to avoid confusion.
SACC	• Provide references to clarify and support EPA approach of regarding reduced brain weight as neurotoxic effect without regard to body weight. The basis for this standard is not clear. References to primary literature that support this view should be clarified. (page 43)	Per EPA (1998) Guidelines for Neurotoxicity Risk Assessment, a change in brain weight is considered to be a biologically significant effect, regardless of change in body weight, because in contrast to many other organs and tissues, brain weight is generally protected during under-nutrition or weight loss. As a result, the guidelines consider it inappropriate to dismiss changes in absolute brain weight that occur without corresponding changes in brain:body weight ratio.
SACC	• Regarding page 189, Table 4-3 – Provide the logic for choosing the specific HEDs. Reference and provide the calculations between HCs and HEDs. It is currently unclear. Use and formulation of a table may be helpful.	Table 4-3 shows the use scenarios, populations of interest and toxicological endpoints for assessing occupational risks from acute exposure to 1-BP. The HECs shown are those selected as PODs for acute exposure in Section 3.2.10.1, the dose-response assessment for non-cancer endpoints. The dermal HEDs were calculated from the HECs as shown in Section 3.2.10.4. Table 3-8 showing the HECs/HEDs carried forward to the risk characterization is included in Section 3.2.10.4.

SACC	• The term “deviation” is confusing as ± 1standard deviation (SD) is used for continuous data and 1, 5, or 10% level of a 95% confidence interval (CI) is used. Consider using another term.	This appears to be referring to use of the term “relative deviation” for percent changes in BMR for continuous variables. This is standard terminology for EPA BMD modeling and BMDS software.

Human Health Risk Characterization		
Charge Question 6.1: Please comment on the assumptions, strengths and weaknesses of the MOE approaches used to estimate the non-cancer risks to workers and occupational non-users (e.g. adults of reproductive age) following acute inhalation exposures to 1-BP, including the MOEs presented in the document. Specifically, please suggest alternative data that could be used. Please comment on the selection of uncertainty factor values in deriving the benchmark MOE for acute inhalation exposures. **Charge Question 6.2:** Please comment on the assumptions, strengths and weaknesses of the MOE approaches used to estimate the non-cancer risks to consumers following acute inhalation exposures to 1-BP, including the MOEs presented in the document. Specifically, please suggest alternative data that could be used. Please comment on the selection of uncertainty factor values in deriving the benchmark MOE for acute inhalation exposures. **Charge Question 6.3:** Please comment on the assumptions, strengths and weaknesses of the MOE approaches used to estimate the non-cancer risks to workers and occupational non-users following chronic inhalation exposures to 1-BP, including the MOEs presented in the document. Please comment on the selection of uncertainty factor values in deriving the benchmark MOE for chronic inhalation exposures. **Charge Question 6.4:** Please comment on the assumptions, strengths and weaknesses of the approach used to estimate extra lifetime cancer risks to workers which EPA-derived from an inhalation unit risk based on lung tumors in female mice for estimating incremental or extra individual lifetime cancer risk. **Charge Question 6.5:** Please comment on whether the risk characterization has adequately described the assumptions, uncertainties and data limitations in the methodology used to assess risks from 1-BP. Please comment on whether this information and the risk conclusions are presented in a logical, transparent manner and provide suggestions that could increase clarity in the risk characterization. **Charge Question 6.6:** Please comment on whether the risk characterization has adequately identified and characterized the "potentially exposed or susceptible subpopulations" (PESS) based on a thorough review of the reasonably available 1-BP exposure and health effects information on both potentially exposed and biologically susceptible subpopulations.		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 6**	**EPA/OPPT Response**
Exposure characterization is incomplete		
SACC	**SACC COMMENTS:** • Present air concentrations at target risks/MOEs for a few key exposure scenarios. For example, an 8-hour TWA worker and also a residential scenario child 24/7 exposure scenario. This is to state, present air concentrations associated with 10^{-6} cancer risk and MOE of 100 or 1000 for non-cancer effects for residential exposure scenarios that are protective for lifetime 24/7 exposures including for children. This type of benchmark can help risk managers and the public interpret the air concentrations that might be considered acceptable in the various worker and consumer scenarios, and to place new measurements that may be	As explained in Section 5.1.2.2 of the Draft Risk Evaluation, EPA relied on NIOSH guidance (Whittaker et al., 2016) when choosing the 10^{-4} cancer risk benchmark to evaluate risks to workers from methylene chloride exposure. NIOSH's mandate, on pg iii of Whittaker et al. (2016), is to: "… describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." Although NIOSH guidance, p. 20, states that: "exposures should be kept *below* a risk level of 1 in 10,000, *if practical* [emphasis added]" EPA adheres to the 1 in 10,000 benchmark during the risk evaluation stage for TSCA chemicals for

	made. In this draft risk evaluation, decreased live litter size and increased post implantation loss (WIL Research, 2001) were used to assess risk from acute exposure to 1-BP. These specific developmental effects were considered the most sensitive HEC/dermal HED identified for an acute exposure duration and are considered to be biologically relevant to the potentially exposed or susceptible subpopulation (*e.g.*, adults of reproductive age and their offspring).	workers. It is important to note that $1x10^{-4}$ is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks or factors as appropriate. See Section 5.1.1.2 of the Risk Evaluation for additional information. EPA has consistently applied a cancer risk benchmark of $1x10^{-4}$ for assessment of occupational scenarios under TSCA. This is in contrast with cancer risk assessments for consumers or the general population, for which $1x10^{-6}$ is applied as a benchmark (Section **Error! Reference source not found.**). Note that other precedents (*e.g.*, Office of Water; Office of Air) are the basis for cancer benchmarks to be used for risks to the general population, but EPA did not quantitatively evaluate such scenarios for 1-BP. EPA has considered susceptible subpopulations when evaluating these risks, as directed by TSCA. Specifically, EPA used the lower 95th confidence bound on the cancer slope, which accounts for variability and uncertainty in individuals' tumor responses, including susceptible subpopulations. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed.
50	**PUBLIC COMMENTS:** • The model input parameters for consumer use modeling are unrealistic. 1-BP is rarely found in consumer products although EPA identified a number of "Consumer Use Products."	Sections 2.3.2.2 and 2.3.2.6 provides a discussion about the model input parameters, SDS and Westat Survey data utilized for model inputs and the assumptions and uncertainties associated with use of these data. Regarding the presence of 1-BP in consumer products, EPA identified multiple products which are both available for purchase by consumers and EPA found evidence of consumer use based on marketing and price of similar consumer products. These products were the bases for selecting input parameters such as weight fraction of chemical in product (most products contained 50 to 90 percent 1-BP by weight). EPA believes utilizing the weight fractions and other data associated with these products is realistic and representative of actual or potential consumer exposure. Finally, to help minimize potential biases toward high-end exposure scenarios for certain durations, mass used or weight

		fraction of 1-BP in products, EPA chose to evaluate consumer exposure across a spectrum of durations/mass used including the 10th, 50th, and 95th percentile data as identified within the Westat Survey as well as the range of product specific weight fractions identified through review of multiple product SDSs.
30, 36, 48, 34	**PUBLIC COMMENTS:** • EPA failed to consider the health risks associated with 1-BP exposures in ambient air, water, and soil. EPA cannot disregard 1-BP exposures merely because they could be regulated under other environmental laws. Instead, TSCA requires EPA to evaluate all risks associated with a chemical's known, intended, and reasonably foreseen conditions of use. Without taking account of all sources of exposure, it is not possible to derive an accurate estimate of the overall human health and environmental burden from this chemical.	As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA. EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment.

		As stated in the Section 2.3.1.21 of the Risk Evaluation, Solid wastes containing 1-BP may be regulated as a hazardous waste under RCRA waste code D001 for ignitable liquids (40 CFR 261.21). 1-BP may also be co-mingled with solvent mixtures that are RCRA regulated substances. These wastes would be either incinerated in a hazardous waste incinerator or disposed to a RCRA Subtitle C hazardous waste landfill. Some amount of 1-BP may be improperly disposed as municipal wastes in RCRA Subtitle D landfills, although they are likely to be a small fraction of the overall waste stream. 1-BP migration from RCRA Subtitle C landfills or RCRA Subtitle D municipal landfills will be mitigated by landfill design (double liner, leachate capture for RCRA Subtitle C landfills and single liner for RCRA Subtitle D municipal landfills) and requirements to adsorb liquids onto solid adsorbent and containerize prior to disposal. As stated in the Problem Formulation, releases to RCRA Subtitle C and Subtitle D landfills were not included in this Risk Evaluation. Additionally, while TSCA Section 6(b)(4)(F)(ii) does not require aggregation of exposures, EPA did consider aggregating dermal and inhalation exposures. The final publication of the Risk Evaluation has additional language to Section 4.4.2 regarding aggregating dermal and inhalation exposures. In short, aggregating exposures from multiple routes could inappropriately overestimate total exposure, as simply adding exposure from different routes without an available PBPK model for those routes, would compound uncertainties concerning the true internal dose.
30, 36, 49	**PUBLIC COMMENTS:** • EPA's rationale for excluding a urinary metabolite of 1-BP (N-Acetyl-S-(n-propyl)-L-cysteine, or AcPrCys) as a biomarker of general population exposure does not have valid scientific basis. • EPA overlooked evidence of widespread exposure to 1-BP. Biomonitoring studies have detected a urinary metabolite of 1-BP in most of the people tested, including 99% of pregnant women. Despite describing this metabolite as "a valid biomarker for 1-BP exposure," EPA did not consider these background exposure levels in its dose response	For the purpose of the 1-BP Risk Evaluation, EPA is not using N-acetyl-S-(n-propyl)-L-cysteine as a biomarker. As noted by the SACC, N-acetyl-S-(n-propyl)-L-cysteine is also a metabolite of several other compounds. The uncertainties associated with various biomarkers of exposure are discussed in Section 3.2.4 of the Risk Evaluation.

	analysis, claiming that, in 2016, the peer review panel for a prior 1-BP risk assessment had advised against using such data. • EPA overlooked evidence of widespread exposure to 1-BP based on biomonitoring detection of a urinary metabolite of 1-BP. EPA must consider this bio-monitoring data to establish background levels of 1-BP and to evaluate risks to potentially exposed and susceptible subpopulations. The minutes from that Chemical Safety Advisory Committee meeting supported the use of biomarker data. Also, acute 1-BP exposures need to be considered.	
Need to evaluate cancer risks from acute 1-BP exposures		
SACC, 30, 47	**SACC COMMENTS:** • Describe in detail why short-term exposures to 1-BP and the increased risk to cancer were not addressed. **PUBLIC COMMENTS:** • EPA failed to evaluate cancer risks from acute 1-BP exposures. The explanation EPA provided for not estimating cancer risks following acute exposures (because the relationship is not known between a single short-term exposure to 1-BP and the induction of cancer in humans) is fundamentally inconsistent with EPA's Guidelines for Carcinogen Risk Assessment and the linear extrapolation that EPA purports to apply. • EPA's current approach assumes acute exposures to 1-BP, including to consumers, pose zero cancer risk – an assumption that is clearly not warranted based on the weight of the evidence. EPA needs to apply an extrapolation that provides a scientifically sound estimate for cancer risk from acute and short-term exposures to 1-BP.	The Risk Evaluation for 1-BP does not estimate extra cancer risks for acute exposures because the relationship between a single short-term exposure to 1-BP and the induction of cancer in humans has not been established in the current scientific literature. The 2005 Carcinogen Risk Assessment Guidance states: "Use of short-term data to infer chronic, lifetime exposures should be done with caution. Use of short-term data to estimate long-term exposures has the tendency to underestimate the number of people exposed while overestimating the exposure levels experienced by those in the upper end (*i.e.*, above the 90^{th} percentile) of the exposure distribution." Additionally, based on a linear dose-response assuming equivalent contribution of risk over time, cancer risk is evaluated based on lifetime average daily concentration/dose. As explained in the Risk Evaluation, Section 3.2.8.2.1, according to the NRC (2001), "There are no adopted state or federal regulatory methodologies for deriving short-term exposure standards for workplace or ambient air based on carcinogenic risk, because nearly all carcinogenicity studies in animals and retrospective epidemiologic studies have entailed high-dose, long-term exposures. As a result, there is uncertainty regarding the extrapolation from continuous lifetime studies in animals to the case of once-in-a-lifetime human exposures. This is particularly problematical, because the specific biologic mechanisms at the

		molecular, cellular, and tissue levels leading to cancer are often exceedingly diverse, complex, or not known. It is also possible that the mechanisms of injury of brief, high-dose exposures will often differ from those following long-term exposures. To date, U.S. federal regulatory agencies have not established regulatory standards based on, or applicable to, less than lifetime exposures to carcinogenic substances."
Problems leading to underestimating risk		
53	**PUBLIC COMMENTS:** • EPA's misuse of critical risk assessment elements such as NOAEL / LOAEL could lead to an underestimation of risk. A point of departure (POD) of a benchmark dose (BMD) at 1% is recommended for cancer and non-cancer endpoints. In addition, EPA's misuse of uncertainty factors could lead to an underestimation of risk. National Research Council recommendations for replacing uncertainty factors and MOE with a set of distributions using probabilistic methods should be followed.	EPA relied on existing accepted guidance (*e.g.*, (EPA, 2012a, 2005a, 2002)) to evaluate non-cancer and cancer endpoints in the Final Risk Evaluation of 1-BP. These methods include EPA derived BMCLs for all selected PODs and did not rely on reported NOAELs/LOAELs; appropriate uncertainty factors for non-cancer endpoints; and a linear low-dose extrapolation to model risk from cancer, based on a mutagenic mode of action of action may be operative at least in part for the carcinogenicity of 1-BP. As stated in EPA's Benchmark Dose Guidance, the selection of BMRs is based on a response considered biologically significant. For dichotomous data (i.e. extra risk), a BMR of 10% is standard practice, with lower values used for frank effects or in order to avoid upward extrapolation such as for some epidemiological data. Developmental/reproductive data often supports a BMR of 5% or less. For continuous data either a 1SD change is the default, while identification of biologically significant % change is preferred. EPA followed these guidelines in its BMR selection for all endpoints as explained in Section 3.2.10.1. EPA believes that these methods adequately account for variability and susceptibility within the population, a concern raised by NRC (2009). However, EPA will investigate additional scientific approaches and will consider incorporating more probabilistic modeling into future Risk Evaluations under TSCA.
26, 49	**PUBLIC COMMENTS:** • The draft risk evaluation uses only rat studies on 1-BP to calculate an MOE and does not rely on human studies that showed neurotoxic effects at levels 10X below concentrations producing these effects in rats.	Epidemiological studies were not considered sufficient for dose-response analysis and served as contributions to the weight of evidence. Summary and evaluation of methodological considerations for epidemiological studies are provided in Appendix I.4. Effects observed at ~10x lower values in human

		studies compared to rodents corroborates the POD derivation, because a 10x UF was applied to the rat studies selected for dose-response analysis to account for interspecies differences.
49	**PUBLIC COMMENTS:** • While EPA's draft correctly identifies 1-BP's harmful human health effects, it understates the risks that these effects pose to workers, consumers and vulnerable subpopulations. For example, EPA overlooked significant contributors to consumer exposure, such as concurrent use of multiple products and repeated use scenarios resulting in chronic exposure. Similarly, EPA failed to combine its cancer risk estimates for inhalation and dermal contact, even though these two types of exposure occur concurrently for workers and consumers. Correcting these and other mistakes would significantly increase non-cancer and cancer risks relative to the EPA benchmarks.	The typical frequency of use according to survey data from Westat, 1987 was considered too low to create chronic risk concerns (with the exception of insulation in residential homes). It is unknown whether higher-end use patterns are expected to be clustered or intermittent and how this type of exposure would compare to continuous-exposure toxicity studies. Therefore, while EPA cannot fully rule out that consumers at the high-end frequency of use could possibly be at risk for chronic hazard effects, it is expected to be unlikely. EPA has added this clarification to the consumer risk uncertainties section (Section 4.3.2.1). The final publication of the Risk Evaluation has additional language to Section 4.4.2 regarding aggregating dermal and inhalation exposures. While TSCA Section 6(b)(4)(F)(ii) does not require aggregation of exposures, EPA did consider aggregating dermal and inhalation exposures. Aggregating exposures from multiple routes could inappropriately overestimate total exposure, as simply adding exposure from different routes without an available PBPK model for those routes, would compound uncertainties concerning the true internal dose. Section 2.3.2.6 includes language describing uncertainties associated with EPA's assumption of a single product use. This language recognizes some consumers may utilize more than one product in a single day; however, to consider multiple product uses requires additional assumptions that each of the multiple products used contains 1-BP, as well as multiple products used at the same time, which may not be feasible by a single consumer user. The language also recognizes repeated use scenarios may occur for some do-it-yourself consumer users.
Risk characterization for potentially exposed or susceptible subpopulations		
SACC	**SACC COMMENTS:** • In addition, to protect potentially exposed or susceptible subpopulations, the aggregate exposure should be estimated. (page 63).	EPA has added additional language to Section 4.4.2 justifying why aggregating dermal and inhalation exposures was considered inappropriate. Aggregating exposures from multiple routes could inappropriately overestimate total exposure, as simply adding

		exposure from different routes without an available PBPK model for those routes, would compound uncertainties concerning the true internal dose. TSCA Section 6(b)(4)(F)(ii) directs EPA to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration" in Risk Evaluations. EPA defines aggregate exposures as the combined exposures to an individual from a single chemical substance across multiple routes (*i.e.*, dermal, inhalation, or oral) and across multiple pathways (*i.e.*, exposure from different sources). 40 CFR 702.33. EPA defines sentinel exposures as the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures. 40 CFR 702.33. EPA considered the reasonably available information and used the best available science to determine whether to consider aggregate or sentinel exposures for a particular chemical. EPA has determined that using the high-end risk estimate for inhalation and dermal risks separately as the basis for the unreasonable risk determination is a best available science approach. There is low confidence in the result of aggregating the dermal and inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk.
36, 34, 47	**PUBLIC COMMENTS:** • There is no question that 1-BP presents unreasonable risks. Only by considering all exposure pathways and all relevant data can EPA evaluate and protect vulnerable subpopulations from those risks. The draft risk evaluation fails to do so. Examples of potentially exposed subpopulations within the general population that EPA has ignored include: people living in proximity to	The PESS referred to by the commenter would be considered part of the general population. As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on

	manufacturing, processing, use and disposal sites or other sources of release of or contamination by 1-BP; infants, children, pregnant women, lactating women, women of child bearing age, and men of childbearing age	exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA. EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment.
35	**PUBLIC COMMENTS:** • EPA also acknowledges that dry cleaners do not fall under and regulatory requirements with regard to engineering controls to protect their workers from 1BP.	EPA assumes the comment pertains to PPEs and not engineering controls to protect workers. The unreasonable risk determination for 1-BP did not assume respirator use for the dry cleaning COU.
35, 49, 47	**PUBLIC COMMENTS:** • The EPA does not take into account children who are too young for or not in school and who may be in the dry-cleaning facility for the entire time an adult is present. In addition, the EPA does not take into account children in a family-owned dry cleaner are likely to spend their outside of school time in the business, which greatly eclipses their	EPA acknowledges that exposure to children could occur in small, family-owned businesses such as dry cleaners. However, it is unclear whether children are actually present at any of the eight remaining dry-cleaning facilities using 1-BP in the United States. As explained in the Draft Risk Evaluation, the acute health domains (developmental effects) are not applicable to children. Further, there is uncertainty as to the frequency or duration of such

	in-school hours. EPA did not assume that exposure to children would be chronic despite the fact that they will be present in the shop over much of their lives, and likely as they get older, at increasing times and levels of exposure due to helping out their family members. • While EPA calculates acute exposure to children at family dry cleaners, it stops short of actually calculating the associated risk. EPA assumes its risk estimates for pregnant women are protective of all lifestages. However, this assumption is in direct contradiction to the recommendations of the CSAC in 2016 provided in its comments on the agency's 2016 1-BP Work Plan Risk Assessment. The agency should have, at the very least, evaluated the risk to children based on other endpoints, because even using less sensitive endpoints may have identified very real risks to children from 1-BP exposure.	exposure, and whether it would be chronic in nature. For additional information, commenters can refer to Tables 4-3 through 4-5 (that describe the use scenarios, populations of interest and toxicological endpoints for assessing occupational/consumer risks following acute and chronic exposures to 1-BP), and Sections 3.2.8.5 and 4.2.3 (that provide additional explanations regarding risks to children who may be present in the workplace, *e.g.,* dry cleaners) of the Risk Evaluation. In summary, for occupational exposures, EPA considered effects following acute exposures to 1-BP (decreased live litter size and increased post implantation loss) as the most sensitive HEC/dermal HED identified for an acute exposure duration, which were considered to be biologically relevant to the potentially exposed or susceptible subpopulation (*i.e.,* adults of reproductive age and their offspring). Further support for using this endpoint for acute (short-term) exposures is the fact that the male and female reproductive effects (in the F_0 males and females) collectively contributing to the decreases in live litter size, all occurred within a short window of exposure between ovulation and implantation. While exposures during other lifestages (such as in childhood) may cause similar or related effects, without specific information on the mechanism of action or developmental windows of sensitivity for these specific developmental effects, there are uncertainties in extrapolating these effects for other lifestages in order to refine dose estimates for these additional lifestages. For chronic exposures, EPA considered exposures to younger aged children spending time in the workplace (*e.g.,* family-owned business) as unlikely to be chronic in nature. As a result, EPA did not assess risks to children who may be present in the workplace (*e.g.,* dry cleaners). Since risk estimates were based on the most robust and sensitive endpoint, which is applicable to pregnant women, EPA expects that risk estimates based on this endpoint are protective of any other acute hazard that could be applicable to children lifestages.
35	**PUBLIC COMMENTS:** • EPA's approach under TSCA is inconsistent with current	EPA considers both exposure (Section 2.4) and hazards (Section 3.2.10.3) in evaluating potentially exposed or susceptible subpopulation (PESS)s. EPA has added text outlining additional

	science. Established science indicates that both biological and social factors can make people more susceptible to chemicals, but EPA is not integrating this information to identify and protect vulnerable groups such as children, pregnant women, the elderly, and workers. This is evident in its refusal to ban methylene chloride paint strippers for industrial and commercial use despite the deaths of a dozen workers caused by the chemical	factors affecting susceptibility: "Factors affecting susceptibility examined in the available studies on 1-BP include lifestage, gender, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and nutrition status." These additional susceptibility factors that are not explicitly quantified in the hazard assessment are expected to be accounted for through the use of a 10x UF to account for human variability.
47	**PUBLIC COMMENTS:** • EPA limits its analysis of greater exposure to workers, occupational non-users, and consumers, and EPA largely ignores the greater exposure experienced by individuals living in proximity to conditions of use. EPA provides no analysis of whether those living in proximity to the conditions of use are at greater risk due to greater exposure. EPA should identify people living near disposal sites as potentially exposed or susceptible subpopulations. The CSAC found that exclusion of chronic exposure of the general public near facilities using 1- BP is a major limitation of this risk assessment. EPA should be analyzing communities who live or work near past manufacturing, processing, distribution, or use sites, even if those activities have ceased. • EPA cannot accurately evaluate potentially exposed or susceptible subpopulations such as fence line communities if EPA excludes the vast majority of exposure pathways leading to their greater exposure. EPA fails to recognize that environmental justice communities have not historically been protected by other environmental statutes and are often disproportionately exposed to chemical substances through disposal and other conditions of use.	EPA considers both exposure (Section 2.4) and hazard (Section 3.2.10.3) in evaluating potentially exposed and susceptible subpopulation (PESS)s. EPA has added text outlining additional factors affecting susceptibility: "Factors affecting susceptibility examined in the available studies on 1-BP include lifestage, gender, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and nutrition status." These additional susceptibility factors that are not explicitly quantified in the hazard assessment are expected to be accounted for through the use of a 10x UF to account for human variability. The PESS referred to by the commenter would be considered part of the general population. As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk

		Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA. EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment.
Underestimation of occupational risk		
24, 26, 35, 48, 34, 49	**PUBLIC COMMENTS:** • EPA is underestimating risk by assuming workers will use personal protective equipment. EPA's overall appraisal of worker exposures underestimates the extent of exposures to 1-BP. There are currently no regulatory requirements for installing engineering controls to reduce 1-BP emissions and associated worker exposures at dry cleaning facilities. EPA's determinations of unreasonable risk for 1-BP should be based on workplace exposure levels in the absence of PPE – an approach that requires EPA to conclude that nearly all workers face unreasonable risks.	EPA's approach for developing exposure assessments for workers is to use reasonably available information and expert judgement. EPA considers each condition of use and constructs exposure scenarios with and without PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. For the purposes of determining whether a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on this information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. In consideration of these uncertainties and variabilities in PPE usage, including the duration

		of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. The OSHA regulations at 29 CFR 1910.132 require employers to assess a workplace to determine if hazards are present or likely to be present which necessitate the use of personal protective equipment (PPE). If the employer determines hazards are present or likely to be present, the employer must select the types of PPE that will protect against the identified hazards, require employees to use that PPE, communicate the selection decisions to each affected employee, and select PPE that properly fits each affected employee.
54	**PUBLIC COMMENTS:** • EPA's 1-BP risk evaluation considers one increased incidence of cancer in every 10,000 to 1,000,000 people as evidence of unreasonable risk for the general public, but for workers characterizes increased cancer risks for up to 1 in 10,000 workers as reasonable and not warranting regulation.	As noted in the Draft Risk Evaluation (Section 5.1.1), EPA relied on NIOSH guidance (Whittaker et al., 2016) when choosing the 10^{-4} cancer risk benchmark to evaluate risks to workers from 1-BP exposure, NIOSH's mandate, on p. iii of Whittaker et al. (2016), is to: "… describe exposure levels that are sage for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." Although NIOSH guidance, p.20m states that: "exposures should be kept below a risk level of 1 in 10,000 *if practical* [emphasis added]" EPA adheres to the 1 in 10,000 benchmark during the risk evaluation stage for TSCA chemicals. It is important to note that $1x10^{-4}$ is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks or factors as appropriate. EPA has consistently applied a cancer risk benchmark of $1x10^{-4}$ for assessment of occupational scenarios under TSCA. As mentioned by the commenter, this is in contrast with cancer risk assessments for consumers or the general population, for which $1x10^{-6}$ is applied as a benchmark (Section **Error! Reference source not found.**). See Section 5.1.1.2 of the Risk Evaluation for additional information. Note that other precedents (*e.g.*, Office of Water; Office of Air) are the basis for cancer benchmarks to be used for risks to the general population, but EPA did not quantitatively evaluate such scenarios for 1-BP. EPA has considered susceptible subpopulations when evaluating these risks, as directed by TSCA. Specifically, EPA used

		the lower 95th confidence bound on the cancer slope, which accounts for variability and uncertainty in individuals' tumor responses, including susceptible subpopulations. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, 1x10^{-6} to 1x10^{-4}) depending on the subpopulation exposed.
46	**PUBLIC COMMENTS:** • Short-term studies may not be representative of the effects in humans experiencing chronic exposure. Cal/OSHA recommends EPA use an additional uncertainty factor in calculating the benchmark MOE for neurological effects.	Explanations of UF determination have been added to Section 3.2.10.1.3. In short, effects were seen at similar concentrations between the short-term study by Honma, et al., (2003) and the 12-week Ichihara et al., (2000) study, indicating that an adjustment for longer exposure duration was not required.
Clarifications needed		
SACC	**SACC COMMENTS:** • The rationale for the decision to use the reprotoxic effects instead of neurotoxic effects should be included. Neurotoxicity effects might not have been sufficiently discussed. This is especially true given the noted neurotoxic effects from human exposure, even if the MOE does not differ from that calculated reproductive endpoints. Also, the rationale for the lack of follow-up on the immuno-toxic effects noted in two mouse studies should be provided.	The reproductive endpoint was a more sensitive and robust POD than the neurotoxicity endpoint. Risk estimates for all PODs are provided in the supplemental risk calculator, however only risk estimates for the most robust and representative chronic endpoint were provided in the body of the Risk Evaluation in order to succinctly present risk for the COU overall. Text was added regarding the rationale for exclusion of the immune studies from the dose-response assessment.
25	**PUBLIC COMMENTS:** • EPA should clarify how the overestimation of exposure (based on the data used) was considered in the final risk evaluation decision within the MOE calculation.	EPA characterizes uncertainties associated with both exposure and risk estimates throughout the Risk Evaluation. EPA provides occupational risk estimates at both high end and central tendency and consumer risk estimates at low, medium, and high intensity use. EPA believes that this range adequately captures the range of estimated exposures associated with each COU.
26	**PUBLIC COMMENTS:** • EPA is changing the numerator of the MOE fraction from (a) a level acceptable for residents, consumers, or workers to (b) a level N orders of magnitude above the acceptable level. With this change, now the MOE has to be greater than 10^N to be acceptable. A hypothetical MOE of 90 is not "almost 100"—it is a case of unacceptably high exposure. In other words, the use of "the MOE needs to be	The commenter appears to be comparing the MOE approach that is used for the human health risk assessment with the RQ approach that is used for the environmental risk assessment or the RfC/RfD approach used for IRIS hazard assessments. With an MOE approach, the benchmark MOE represents target value for comparing hazard values to estimated exposure when accounting for all UFs. In the example, an MOE of 90 with benchmark of 100 would be equivalent to an RQ of 1.11, and the benchmark of 100

	at least 100" can easily lead to statements like "we've provided a margin of safety of 90, which is almost as good as 100." The SACC needs to encourage EPA to rethink this confusing and circuitous exposition method.	would be equivalent to the ratio of the POD/RfC.
31	**PUBLIC COMMENTS:** • Process EPA used to come up with radically different levels of "risk" using essentially the same data and the same methodology as the previous BMD analysis should be reviewed in depth.	The 2016 1-BP Draft Risk Assessment was completed prior to passage of updated TSCA, which requires a more rigorous evaluation of what data and methodologies comprise "the best available science." The only major change from the 2016 Draft Risk Assessment is the reduction of the UFs for neurotoxicity from Honma et al., (2003) from 10 to 1 because effects were seen at similar concentrations in longer-duration studies (2000), indicating that exposures in the longer-term animal studies are not reasonably expected to cause equivalent nervous system effects at a lower concentration than the 3-week study by Honma et al., 2003.
Recommendations to Improve the Selection of Uncertainty Factor Values in Deriving the Benchmark MOE for Acute and Chronic Inhalation Exposures (Listed on pages 57-59)		
SACC	**SACC COMMENTS:** • The use of the chronic study to determine acute exposure risk was described by the EPA as a very health-protective effect. However, this approach is not necessarily accurate, and could overestimate risks to workers and consumers following acute exposure, especially for those below reproductive age. This point, as well as more about the uncertainties of using the chronic study in this way, needs to be expanded upon. • When describing the decreased live litter size and post-implantation loss in F_0 females there are different HECs provided for acute vs chronic exposure. This is explained by "HECs are calculated by duration adjustment and a human equivalent DAF. The adjusted POD is the POD x duration adjustment used for the duration adjustment was an 8 hours/day exposure for occupational exposure scenarios and 24 hours exposure for consumer exposure scenarios. For acute exposure the duration adjustment was (hours per day exposed/8) and for chronic exposure (occupational exposure) was (hours per day exposed/8) x (days per week exposed/5) to reflect a 40-hour work week." This description requires clarification.	In Section 4.3.4.2, EPA states that the risk estimates apply only to individuals age 16 and older for both occupational and consumer settings. Therefore, the developmental endpoints would be applicable to the assessed populations. While consumer exposure may apply to other lifestages, the commenter is correct that the quantitative risk estimates can only be directly tied to women of reproductive age. This discussion has been expanded and clarified in the Risk Characterization Approach, Section 4.2.1. The headers on Table 3-8 and associated footnotes have been updated to add additional clarification. PODs based on air concentrations are adjusted to a Human Equivalent Concentration based on the equivalent dose to get the same toxicological effect for a given exposure duration. Based on adjustments of Concentration x Time = constant, original PODs were adjusted to 8hrs/day, 5days/week for chronic occupational scenarios and continuous exposure for chronic consumer scenarios. For acute scenarios, the days/week factor was eliminated from the adjustment.

	• In utero implantation loss and live litter size reduction are separate, but not independent endpoints. The EPA should clarify this point and justify the use of both endpoints.	EPA considered both implantation loss and decreased litter size. The POD selected was chosen to be protective for both effects.
	• Statements in the draft risk assessment such as "However, the short half-life for 1-BP suggests there will not be increasing body burden over multiple exposure days, therefore, no duration adjustment is needed." This statement needs clarifying. Does it mean that because 1-BP has a relatively short half-life *in vivo* that duration of exposure over time does not need to be taken into account or that the EPA is not concerned about an accumulated body burden?	The text regarding extrapolation of a repeated-dose study to an acute exposure scenario has been modified to the following for improved clarity: "The short half-life for 1-BP suggests there will not be increasing body burden over multiple exposure days, therefore, effects following single-day acute exposure can be reasonably expected to occur at the same dose as repeated exposures and no duration adjustment is needed."
	• Presentation of the findings within the Executive Summary will be confusing for most readers because, for non-cancer risks, exposures needed to be "above" benchmarks (*e.g.*, MOE=100) to be acceptable; and for cancer risks, exposures needed to be below benchmarks (*e.g.*, lower than 10^{-4}, 10^{-6}) to be acceptable. While this presentation can be understood by technical experts, risk managers and the public are unlikely to be able to comprehend it. Create a figure listing every scenario along the X dimension and with a two-part Y dimension (cancer and non-cancer) indicating the agency's acceptable and unacceptable risk for MOE values for each scenario. An example is provided in Table 1 of the SACC FINAL REPORT (page 59)	The Executive Summary has been updated to follow the format of subsequent Draft Risk Evaluations. Additionally, Section 5 (Unreasonable Risk Determination) has been revised to clarify the basis for the unreasonable risk determination of each COU. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumes use of PPE, what APF or PF is assumed, and how the risk estimates support or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk.
	• The rationale for the decision to use the reprotoxic effects instead of neurotoxic effects should be included. Neurotoxicity effects might not have been sufficiently discussed. This is especially true given the noted neurotoxic effects from human exposure, even if the MOE does not differ from that calculated reproductive endpoints. Also, the rationale for the lack of follow-up on the immuno-toxic effects noted in two mouse studies should be provided.	The developmental POD of post-implantation loss is slightly more health-protective than the neurotoxicity endpoint (24 vs 25 occupational ppm, identical consumer ppm). MOEs for all selected chronic endpoints were presented in the risk characterization section. In the Final Risk Evaluation, MOEs based on the developmental POD are presented in the Risk Conclusions section because it is the most health-protective value.
Recommendations to Improve the Draft Risk Evaluation (Listed on page 62)		
SACC	**SACC COMMENTS:** • Include a section on key assumptions, limitations, and	Section 4.3 covers Assumptions and Key Sources of Uncertainty for the occupational exposure, consumer exposure, hazard, and risk

	uncertainties that may affect the determination of risk rather than a long discussion of unprioritized and less important items. • Follow the recommendations outlined in the Committee's responses to the other questions that address these issues. • Include additional information and references to support assumptions. Quantify assumptions, key uncertainties, and data limitations as much as possible. Provide that comparison in this section, for human health referencing Table Apx I-1, Pp. 346-347. This is evidence integration and would be useful for all endpoints used to characterize risk. If HECs are similar or close to human data, it could support the use and magnitude of UFs in MOE evaluation and characterization (or not). EPA should attempt to corroborate MOEs with human experience in the risk assessment. • Use Bayesian methods for the development and application of Uncertainty Factors (Simon et al. 2016).	characterization. All these uncertainties are considered in the determination of unreasonable risk. EPA used reasonably available information for the Risk Evaluation of 1-BP. Due to time constraints EPA cannot implement a Bayesian framework comprehensively for this risk evaluation; however, EPA will consider incorporating more probabilistic modeling into future risk evaluations under TSCA.
Recommendations to Improve the Draft Risk Evaluation (Listed on pages 63-64)		
SACC	**SACC COMMENTS:** • Place the DRE in one location with a clearer statement of which groups were identified and how it was addressed, for example, PowerPoint slide #78 in the OPPT technical presentation by Dr. Katherine Anitole/EPA/OPPT/RAD (refer to Slide Presentation #78 below).	The Risk Characterization Approach (Section 4.2.1) provides an overview of all populations of interest in the Risk Evaluation for human health.
	• Place multiple mentions of PESS into headings so they would be easier to find.	There are distinct PESS sections for exposure (Section 2.4), human health hazard (Section 3.2.10.3), and risk characterization (Section 4.4.1).
	• Consider aggregate exposure through multiple pathways and routes of exposure from multiple sources. • Aggregate exposures should be estimated to optimally characterize the risk, if risks are not characterized through TSCA.	EPA has determined that using the high-end risk estimate for inhalation and dermal risks separately as the basis for the unreasonable risk determination is a best available science. There is low confidence in the result of aggregating the dermal and inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk.

	• Add additional PESS within the DRE. • Refer to SACC (page 64) for Figure 1: OPPT Technical Presentation – Overview of 1-Bromopropane Risk Evaluation: PowerPoint Slide number 78: Potentially Exposed or Susceptible Subpopulations.	The following groups have been added to Section 2.4 based on potentially elevated exposure: people with implantable prosthetics and people who live near 1-BP releasing facilities. The following factors have been added to Section 3.2.10.3 for consideration: lifestage, gender, genetic polymorphism, preexisting health status, lifestyle factors, and nutrition status.
Other		
47	**PUBLIC COMMENTS:** • EPA should have included an additional uncertainty factor for "the uncertainty associated with extrapolation from animal data when the database is incomplete."	There is no universal list of hazard data required when evaluating chemical risks under TSCA. Furthermore, for 1-BP, EPA has sufficient, reasonably available hazard information to conduct a risk evaluation and support the use of the chosen hazard endpoints. Therefore, EPA did not use a database uncertainty factor in the 1-BP Risk Evaluation.

General Risk Characterization		
Charge Question 7.1: Please comment on the objectivity of the underlying data used to support the risk characterizations and the sensitivity of EPA's conclusions to analytic assumptions. **Charge Question 7.2:** Please comment on the characterization of uncertainties and assumptions including whether EPA has presented a clear explanation of underlying assumptions, accurate contextualization of uncertainties and, as appropriate, the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios. **Charge Question 7.3:** Please provide information on additional uncertainties and assumptions that EPA has not adequately presented. **Charge Question 7.4:** Please comment on whether the information presented supports the findings outlined in the draft risk characterization section. If not, please suggest alternative approaches or information that could be used to develop a risk finding in the context of the requirements of EPA's Final Rule, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726).		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 7**	**EPA/OPPT Response**
Alternatives to 1-BP		
28	**PUBLIC COMMENTS:** • Unlike 1-BP, Honeywell's alternative, Solstice Performance Fluid does not have reproductive and developmental toxicity classification. The occupational exposure limit (OEL) of trans-1-Chloro3,3,3-trifluoropropene, component of Solstice Performance Fluid, is 800 ppm (WEEL OARS-TWA).	EPA appreciates the information provided regarding alternatives to 1-BP. Such information will be considered during any necessary risk management.
47	**PUBLIC COMMENTS:** • EPA makes no mention of the need for surrogate chemicals to have similar environmental and biological fate as well as chemical and physical properties. Nor does it appear to be planning to compare the chemicals on the basis of any available toxicity information.	EPA acknowledges that when using any surrogate chemical information in its assessment, the physical-chemical properties, environmental and biological fate and available toxicity information are important considerations in determining the appropriateness of using a surrogate in place of the chemical being assessed.
Characterization of uncertainties and assumptions		
SACC	**SACC COMMENTS:** • A broader range of ages for exposed populations and longer exposure lifetimes for all assessed populations. • The diminution in scope between 2016 and 2019, in which general population exposures were excluded, does not instill confidence that objectivity is being maintained in Agency assessments as part of TSCA. To overcome this perception, in cases where environmental or other data are unavailable the Agency should use the "best available science," which would: 1) Use high centile	Where applicable, EPA considered a range of ages (consumer dermal exposure). Occupational and lifetime exposures are based on EPA's current practice for workers 16+ years of age and 78-year lifetime. As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways

	modeled data with appropriate safety factors to account for uncertainty in achieving protection; or 2) Obtain from producers or formulators sufficient data to inform a robust risk assessment. This seems to have been done infrequently for the 1-BP risk determination. (page 65) • Additionally, the Committee recommended that the Agency evaluate uncertainties in each data set and ascribe adjustment or uncertainty factors in the numerical assessments of hazard to account for these uncertainties in the HQs. This has not been done in several instances. Also, the Agency did not clearly state how adjustment factors were selected in the current 1-BP Risk Determination. (page 70) • The lack of consideration for general population exposures excludes a vast extent of the US population (workers, consumers, school children, and other populations) who are exposed to 1-BP, perhaps on a daily basis. The lack of consideration of the general population exposure is concerning given the strong evidence of widespread exposure to a chemical that may be 1-BP based on biomonitoring data. Although the biomonitoring data is not definitive proof of widespread 1-BP exposure, it does add uncertainty to the exposure estimates for workers, ONUs and consumers, in addition to raising concerns about general population exposure. This increased uncertainty should be captured in the exposure assessments. (page 71) • Consider uncertainty in dose response analysis in non-cancer and cancer hazard evaluations. One Committee member recommended that although the Agency intended to be protective, the decision to use a single, high quality study for the dose response analysis in non-cancer and cancer hazard evaluations gives a false sense of precision to the hazard assessments. This uncertainty should also be captured in the overall 1-BP risk determination. (page 65) • Sensitive populations human populations whose risks are undefined and uncharacterized in the 1-BP DRE.	and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Additionally, under TSCA, EPA has utilized a 10x UF to account for human variability (*e.g.*, race/ethnicity). In Section 3.2.5 of the Risk Evaluation, EPA integrates and evaluates both the non-cancer and cancer human health hazard endpoints from the health hazard domains identified. This evidence integration and evaluation uses a weight of the scientific evidence approach wherein the strengths, limitations, uncertainties and relevance of the hazard data were analyzed and summarized across studies, taking into consideration consistency and coherence among animal studies, quality of the studies (such as whether studies exhibited design flaws that made them unacceptable) and biological plausibility. The non-cancer dose-response analysis in the hazard assessment commenced with the review and selection of high-quality toxicity studies that went through systematic review and that reported both adverse non-cancer health effects and quantitative dose-response data. Table 3-2 of the Risk Evaluation identifies key studies carried forward for dose-response analysis for relevant exposure scenarios from multiple adverse outcome domains. The PODs selected were considered the most adverse, sensitive and biologically relevant endpoints from among these high-quality key and supporting studies. As a result, the non-cancer dose-response assessment was organized into five health effect domains: (1) liver; (2) kidney; (3) reproductive; (4) developmental and (5) nervous system. Emphasis on acute/short term inhalation, and repeated-dose inhalation studies were considered most appropriate for hazard characterization and dose-response analysis. Reproductive and developmental toxicity were identified as critical

	• The vast extent of the US population (workers, consumers, school children, and other populations) who are exposed to 1-BP, perhaps on a daily basis.	targets for 1-BP exposure based on a constellation of effects reported across studies, including a two-generation reproduction study (WIL Research, 2001), which showed adverse effects on male and female reproductive parameters, and the developing conceptus. EPA considered adverse effects for 1-BP across organ systems (a comprehensive summary table, Table_Apx J-2, in Appendix J). The full list of effects was screened to those that are relevant, sensitive and found in multiple studies which include the following types of effects: liver toxicity, kidney toxicity, developmental/reproductive toxicity, neurotoxicity, and cancer as described above. Immune effects were not considered further, as the weight of the scientific evidence was not conclusive. In general, adverse effects were observed in all of these systems in rats exposed to 1-BP by inhalation in the range of 100 – 1000 ppm (LOAELs). Using principles of systematic review, EPA selected endpoints from the highest quality studies with the least limitations for both non-cancer and cancer that were amenable to quantitative analysis for dose-response assessment. Based on the WOE analysis, EPA identifies the appropriate toxicological studies to be used for acute and chronic (non-cancer and cancer) exposure scenarios in Tables 3-3 and 3-8.
SACC	• No reproductive or developmental data were included in the environmental exposures. These more sensitive data (Bernot, Brueseke et al. 2005, Saha, Bhunia et al. 2006, Yang, Ibrahim and Sayed 2019, Kang, Kim et al. 2019) would be important for a robust Risk Evaluation. Techniques to include more data with perhaps lower quality by using a weighting process may be valuable in analyzing data for TSCA risk determinations (Solomon & Stephenson, 2017). To this end, The Agency should have obtained and if necessary translated foreign studies to increase the certainty of the aquatic assessment. (page 65)	Regarding the studies referenced in this comment, these do not pertain to the toxicity of 1-BP to aquatic organisms and were therefore not identified during the literature search for this chemical. EPA did not utilize the ECHA summaries in the Final Risk Evaluation. EPA acknowledges the uncertainties that arise from using data summarized in ECHA where the original studies have not been received by EPA or reviewed for data quality in Sections 3.1 and 4.3.4. EPA was unable to obtain the full studies, which are only available via European entities and therefore could not analyze the studies directly for data quality evaluation. . In silico modeling outputs for 1-BP were also added to further characterize potential hazards to aquatic species from 1-BP. While data on reproductive effects to aquatic life were not reasonably available for 1-BP, hazards of 1-BP following chronic exposure were estimated using acute to chronic extrapolation and structural activity relationship (SAR) predictions, both of which are discussed in Section 3 of the

		Final Risk Evaluation.
SACC	• EPA uses a blanket AF (or UF) of 10, with reference to guidance, to capture uncertainty of all intraspecies variability and assumes this is protective. Adjustment factor selection in the environmental exposures requires objective and empirical determination as mentioned in detail within the Committee response to question 4. The ultimate suggestion from that comment is that the Committee requested that the Agency include an Acute to Chronic Ratio approach for fish that is in line with Keinzler et al, 2017. This is more scientifically defensible and also mitigates the uncertainty arising from the extremely limited data sets that are likely to be available for TSCA assessments.	EPA acknowledges that there is uncertainty regarding the use of a single assessment factor to estimate hazards from chronic exposure to 1-BP. Additional context has been added to Section 3 of the Final Risk Evaluation to understand the protectiveness of an ACR value of 10 in the context of reasonably available literature. While an AF of 10 may not be protective for all chemicals and trophic levels, the use of 10 to calculate a concentration of concern for acute and chronic exposures to environmental receptors is consistent with existing EPA methodology for the screening-level assessment of new chemical substances. EPA is in the process of evaluating the body of reasonably available literature on the subject in order to determine whether to revise standards for application of AF and the acute to chronic ratio for the next 20 high-priority substances undergoing risk evaluation. EPA will consider the Keinzler et al., 2017 study in its assessment. Until the body of scientific evidence for assessment factors is evaluated, EPA will continue to use OPPT methodology as cited in the risk evaluation and apply an AF of 5 for acute and 10 for chronic aquatic invertebrate data. EPA considers these AFs to be protective of aquatic invertebrates from acute and chronic exposures to neutral organic substances such as 1-BP, which produce toxicity from simple narcosis.
SACC	• Human health conclusions are quite sensitive to analytic assumptions regarding respirator use and worker training. The frequency of PPE use is quite uncertain especially if view of limitations of OSHA data. The use of PPE can vary significantly. Thus, there is significant uncertainty in assuming that PPE is used correctly. The Committee recommended that the assessment should incorporate better respiratory data, and in the absence of comprehensive OSHA studies, the use of PPE should not be assumed. The dermal exposure assessment showed that only relatively expensive gloves might prevent 1-BP penetration. So, potentially low frequency of glove use would result. In the absence of actual data, PPE use may be less than assumed in the assessment, and uncertainty factors or adjustment factor should be incorporated to minimize the possibility of a false negative risk determination. (page 68)	EPA has outlined its PPE assumptions in Section 4.2 and has supplemented some sources and information on respirator use based on NIOSH surveys in Section 2.3.1.4 of the Risk Evaluation. EPA has also added a table in Section 4.2.2 to make PPE assumptions made for each COU clearer. EPA's approach for developing exposure assessments for workers is to use the reasonably available information and professional judgment. When appropriate, in the Risk Evaluation, EPA will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. Again, while EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. The use of PPE assumptions are described in the unreasonable risk determination for each condition of use, in

		Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA has also outlined its PPE assumptions in Section 5.1. The OSHA regulations at 29 CFR 1910.132 require employers to assess a workplace to determine if hazards are present or likely to be present which necessitate the use of personal protective equipment (PPE). If the employer determines hazards are present or likely to be present, the employer must select the types of PPE that will protect against the identified hazards, require employees to use that PPE, communicate the selection decisions to each affected employee, and select PPE that properly fits each affected employee.
SACC	• Assumptions about PPE use are likely unrealistic for many of the scenarios and so the determination of whether a condition of use results in an acceptable or unacceptable risk should be based on no PPE use, with the possible exception of in a manufacturing facility. (page 66) • That PPE is not always used when making the final risk determination for occupational users.	EPA's approach for developing exposure assessments for workers is to use the reasonably available information. As explained previously, EPA uses exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given condition of use. EPA did assess the risk to workers in the absence of PPE, and those risks are presented in Section 4 Risk Characterization under Table 4-57 Occupational Risk Summary Table. While EPA has evaluated worker risk with and without PPE, as a matter of policy, EPA does not believe it should assume that workers are unprotected by PPE where such PPE might be necessary to meet federal regulations, unless it has evidence that workers are unprotected. For the purposes of determining whether or not a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on reasonably available information and professional judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage, including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties. EPA has also outlined its PPE assumptions in Section 5.1. As explained in the Risk Evaluation, EPA assumes ONUs do not wear

		PPE because they do not directly handle 1-BP. As such, the unreasonable risk determination does not consider the use of PPE for ONUs.
SACC	• Provide more description of consumer uses and uncertainties regarding 1-BP release from consumer products. Consumer uses and associated uncertainties are not well defined in Section 3 of the DRE. There are uncertainties regarding 1-BP release from consumer products that should be included. For example, consumer products data are old, and leaking household product containers have not been considered (see response to charge question 4). Each uncertainty should be described in Section 3 and summarized in Section 4 of the DRE. (page 68)	EPA has expanded its discussion of uncertainties in the Final Risk Evaluation. Some of the examples were already addressed (age of product data, Westat Survey data) in the Draft Risk Evaluation and carried through to the Final Risk Evaluation. EPA did not consider indoor air releases from storage of product containing 1-BP as this is not tied to a particular condition of use and is not in and of itself a consumer condition of use. Additionally, TSCA Section 6(b)(4)(F)(iv) instructs EPA to factor into TSCA risk evaluations "the likely duration, intensity, frequency, and number of exposures under the conditions of use." This suggests that activities for which duration, intensity, frequency, and number of exposures cannot be accurately predicted or calculated based on reasonably available information were not intended to be the focus of TSCA Risk Evaluation. Since reasonably available information was not identified to inform these and other parameters (including off-gassing rates or concentrations) and as recognized by SACC that the absence of data leaves it uncertain how to develop a worst-case scenario, storage of consumer products was not evaluated in this Risk Evaluation.
SACC	• The Agency states, on page 250 of the DRE, "Because of uncertainties inherent in deriving RQ's, values are protective so that the risk estimate can state with a high degree of confidence that RQ values < 1 are not an ecological risk and can be screened out from further analysis." The Committee found this statement is inaccurate. More correctly, the significant uncertainties related to the environmental exposures are reasons that RQs, which approach 1, should not be used to screen out ecological risks. In fact, added adjustment factors are needed during the calculation of RQs (refer to charge question 4). (page 67) • Use of uncertainty factors or adjustment factors to capture uncertainties in Hazard Quotients and Risk Quotients.	EPA acknowledges that there is uncertainty regarding the use of a single assessment factor to estimate hazards from chronic exposure to 1-BP. Additional discussion was added to the environmental exposure section of the Final Risk Evaluation regarding releases to water and associated exposure. This approach is consistent with existing approaches used by EPA in screening-level assessments of chemical substances with the goal of identifying exposure pathways of concern, where AFs are applied to hazard data to account for uncertainties including laboratory to field extrapolation rather than uncertainties in the estimated exposure concentrations. Reasonably available data characterizing aquatic release concentrations of 1-BP indicate very low release concentrations (5 pounds of the 20 million pounds manufactured or processed in a single year).
SACC	• With the widespread use of polyiso insulation, and the	EPA expanded its evaluation of the insulation (off-gassing) condition

	relatively long-term off gassing of the 1-BP as demonstrated in Figures 2-14, the Committee recommended that this source of exposure should receive more attention in the risk assessment, at the very least as an uncertainty factor associated with a possible additional source of 1-BP. (page 70) • Uncertainties related to an apparent underestimation of human exposure to 1-BP from insulation.	of use in the Final Risk Evaluation. This includes two building configurations (crawlspace and full basement), as recommended by SACC, and acute and chronic exposure scenarios due to the potential for 1-BP off-gassing over an extended period of time following installation. Additionally, EPA also conducted a sensitivity analysis for the insulation (off-gassing) condition of use based on temperature variations associated with installation at different times of the year.
SACC	• Uncertainties related to biomarkers and non-specificity of assessment endpoints. • Uncertainty in the assumption that many employees in dry cleaning operations are occupational non-users. • Vapor emissions from open drier doors as a source of increased worker exposure.	EPA appreciates the recommendations and has considered them in finalizing the Risk Evaluation. The discussions of various uncertainty have been updated in both the Uncertainty section as well as throughout the Final Risk Evaluation.
50	**PUBLIC COMMENTS:** • Initial exposure models should be derived from sensitivity analyses and used to identify exposure parameters and assumptions with most uncertainty while higher-tiered models should be used to refine more realistic exposure evaluations. EPA should more clearly note assumptions within each model, especially in dermal exposure calculations were model inputs are not supported by the weight of scientific evidence.	The exposure models used in the Risk Evaluation, including information on the model input parameters, default values, and associated assumptions, are described in detail in the supplemental documents.
34	**PUBLIC COMMENTS:** • EDF disagrees with EPA's decision to use a benchmark cancer risk level of 1 x 10^{-4} to define unreasonable risk to workers and disagrees with EPA that this issue is beyond the scope of the SACC. EPA's unprecedented use of 1 in 10,000 as the cancer risk benchmark for workers also clearly underestimates risk and goes against EPA's longstanding policy "that it should reduce risks to less than 1 x 10-6 for as many exposed people as reasonably possible."	As noted in the Draft Risk Evaluation (Section 5.1.1), EPA relied on NIOSH guidance (Whittaker et al., 2016) when choosing the 10^{-4} cancer risk benchmark to evaluate risks to workers from 1-BP exposure. NIOSH's mandate, on pg iii of Whittaker et al. (2016), is to: "… describe exposure levels that are safe for carious periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." Although NIOSH guidance, p. 20, states that: "exposures should be kept *below* a risk level of 1 in 10,000 *if practical* [emphasis added]" EPA adheres to the 1 in 10,000 benchmark during the Risk Evaluation stage for TSCA chemicals. It is important to note that $1x10^{-4}$ is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks or factors as appropriate. See Section 5.1.1.2 of the Risk Evaluation for additional information.

		EPA has consistently applied a cancer risk benchmark of $1x10^{-4}$ for assessment of occupational scenarios under TSCA. This is in contrast with cancer risk assessments for consumers or the general population, for which $1x10^{-6}$ is applied as a benchmark (Section **Error! Reference source not found.**). Note that other precedents (*e.g.*, Office of Water; Office of Air) are the basis for cancer benchmarks to be used for risks to the general population, but EPA did not quantitatively evaluate such scenarios for 1-BP. EPA has considered susceptible subpopulations when evaluating these risks, as directed by TSCA. Specifically, EPA used the lower 95th confidence bound on the cancer slope, which accounts for variability and uncertainty in individuals' tumor responses, including susceptible subpopulations. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed.
47	**PUBLIC COMMENTS:** • EPA's 1-BP Supplemental File Occupational Risk Calculator shows that these risks [occluded scenarios] are actually quite large. Yet it appears that the risk estimates under occluded conditions are not actually incorporated into the Risk Characterization and Risk Determinations in the draft risk evaluation at all.	See further discussion on occlusion in the Supplemental Information on Occupational Exposure Assessment (EPA, 2019). The occluded scenarios were presented as a what-if scenario. EPA does not know the likelihood or frequency of these scenarios in the workplace and did not calculate risk associated with occluded exposure.
Information/assumptions that EPA has not adequately presented		
SACC	**SACC COMMENTS:** • There are data gaps in environmental and human exposure assessments. The Committee recommended a quantified sensitivity analysis would allow a determination of whether these gaps affect the results. (page 67)	EPA appreciates the comments. For the human exposure assessment, EPA has performed a sensitivity analysis as part of the probabilistic inhalation exposure modeling for certain conditions of use, where data are reasonably available to perform such an analysis. EPA is not pursuing a quantitative sensitivity analysis at this time for other assessments or models.
	• Provide more explanation to clarify why EPA results for workers and ONUs are much higher than ACGIH. The risk evaluation notes that "for most conditions of use, the central tendency and high-end TWA exposures for both workers and ONUs are significantly above the American	The ACGIH TLV is a guideline used in the practice of industrial hygiene and is not a legal standard applicable under TSCA. EPA does not have an explanation of why some measured exposure levels exceed the TLV.

	Conference of Governmental Industrial Hygienists, Threshold Limit Value (ACGIH TLV) of 0.1 ppm" (2.3.1.21). The Committee recommended that this result should be discussed more thoroughly and included in the Executive Summary. (page 66)	
	• Verify accuracy of statements about exceedance of benchmark MOEs. The Committee noted that in several instances, The Agency states that the benchmark MOE were exceeded by "several orders of magnitude." This is inaccurate in each instance. For example, Tables 4-6 (1-2 orders of magnitude), 4-7 (1-2 orders of magnitude), 4-12 (less than one to several), 4-14 (2-4-fold), etc. The agency should verify these data against the overall statements of exceedance. (page 70)	These errors have been addressed in the Final Risk Evaluation.
26	**PUBLIC COMMENTS:** • EPA neglected to address the breakthrough of organic solvents like 1-BP through the carbon or other medium in organic vapor cartridges.	EPA acknowledges that PPEs including respirators with organic vapor cartridges have breakthrough. EPA states in the Risk Evaluation appropriate use of PPEs which require having a change-out schedule.
30, 35, 47	**PUBLIC COMMENTS:** • EPA's failure to evaluate hazards or exposures to the general population is unlawful and violates the plain text of TSCA. Reasonably available information establishes that the general population experiences significant exposures to 1-BP, and it is irrational to ignore those exposures in light of this evidence. Despite the acknowledged uncertainty, EPA still needs to consider NHANES data with regard to this urinary metabolite (BPMA) associated with 1-BP	As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations. EPA has therefore tailored the scope of the risk evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA.

		EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment. Further, although not previously addressed in the Draft Risk Evaluation, EPA considered reasonably available information and qualitatively characterized exposure and risk to the general population from water, sediment, and soil. Additional details can be found in Section 4.5 and Section 5 of the Final Risk Evaluation. For the purpose of the 1-BP Risk Evaluation, EPA is not using BPMA as a biomarker at this time. The uncertainties associated of various biomarkers of exposure is discussed in Section 3.2.4 of the Risk Evaluation.
48	**PUBLIC COMMENTS:** • In its approach to 1-BP and to other risk evaluations, to the extent that use of a chemical has already been reduced due to health and environmental concerns, EPA seems to take the approach of determining that there is no need for regulation, thus creating the conditions for that use to rebound in the future. It is important to consider the ways in which 1-BP could be reintroduced into more widespread use in the absence of regulation specifically designed to prevent this.	As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). EPA believes the TSCA Risk Evaluations should focus on uses and exposure pathways associated with TSCA conditions of use that are not

		subject to other federal statutes because those pathways and conditions of use are likely to represent the greatest areas of concern to EPA. Additionally, for the COUs within the scope of the TSCA Risk Evaluation, EPA determines whether the COU presents an unreasonable risk or no unreasonable risk. If a COU is determined to present unreasonable risk, EPA moves into risk management action.
34, 47	**PUBLIC COMMENTS:** • EPA assumes that Resource Conservation and Recovery Act (RCRA) adequately manages all wastes disposed of in hazardous and nonhazardous waste landfills. In a previous comment on the 1-BP Problem Formulation, EDF raised numerous reasons why this assumption is to be questioned. • It is wholly inappropriate for EPA to simply assume either that there is universal compliance with laws and standards, or that even when complied with, such requirements eliminate all risk such that EPA can ignore the contribution of remaining risks from such regulated activities to the overall risks posed by 1-BP. EPA cannot rely on any assumption of consistent implementation and enforcement of RCRA to ensure that all exposures have been adequately managed. EPA cannot assume that exposure from disposal is zero just because it could be regulated under other authorities.	As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Compliance/non-compliance with statutory requirements outside of TSCA is not a component to consider when conducting Risk Evaluations under TSCA. Compliance/non-compliance issues are addressed under separate enforcement authorities for each statute along with settlement of identified non-compliance issues.
34	**PUBLIC COMMENTS:** • EPA cites an excerpt in the NRC 2001 document as rationale for not estimating cancer risk for acute exposure, but the NRC document has additional guidance on the development of short-term exposure levels that were not considered by EPA. EDF is concerned that EPA did not sufficiently consider such principles related to mode-of-action in arriving at its decision not to model acute cancer risk based on chronic exposure data.	The 2005 Carcinogen Risk Assessment Guidance states: "Use of short-term data to infer chronic, lifetime exposures should be done with caution. Use of short-term data to estimate long-term exposures has the tendency to underestimate the number of people exposed while overestimating the exposure levels experienced by those in the upper end (*i.e.,* above the 90th percentile) of the exposure distribution." Additionally, based on a linear dose-response assuming equivalent contribution of risk over time, cancer risk is evaluated based on lifetime average daily concentration/dose. Acute exposures averaged over a lifetime (or even a lifestage) would be orders of magnitude lower than

		acute or chronic exposure estimates and would result in risk estimates significantly less sensitive than those based on acute endpoints.
49, 47	**PUBLIC COMMENTS:** • While EPA's draft correctly identifies 1-BP's harmful human health effects, it understates the risks that these effects pose to workers, consumers and vulnerable subpopulations	The Risk Evaluation characterizes the risk appropriately and will be the basis upon which future risk management action occurs.
47	**PUBLIC COMMENTS:** • EPA analyzes risk from inhalation exposures and then separately analyzes risk from dermal exposures; EPA never provides any description or analysis that combines these exposures to assess total exposure and determine whether it presents a risk. It is likely that the exposure scenario with the highest risk estimate would actually be inhalation and dermal exposure combined. • EPA's decision to ignore exposures one-by-one rather than look at combined exposure is inherently inaccurate and will invariably lead to an underestimation of exposure and risk.	EPA has determined that using the high-end risk estimate for inhalation and dermal risks separately as the basis for the unreasonable risk determination is best available science. There is low confidence in the result of aggregating the dermal and inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk.
47	**PUBLIC COMMENTS:** • For cancer risk from dermal exposure, EPA found excessive risk in every occupational scenario it examined – even using its very permissive 1 in 10,000 benchmark. Yet, when it comes to the risk determinations, EPA finds no unreasonable risk in several of these scenarios. EPA's failure to make an unreasonable risk determination will mean it will then lack any authority to require that the gloves it assumed will be used are actually used. • For both the "unreasonable risk" and "no unreasonable risk" determinations, EPA's unwarranted approach raises major policy concerns.	As noted in the Draft Risk Evaluation (Section 5.1.1), EPA relied on NIOSH guidance (Whittaker et al., 2016) when choosing the 10^{-4} cancer risk benchmark to evaluate risks to workers from 1-BP exposure. NIOSH's mandate, on pg iii of Whittaker et al. (2016), is to: "… describe exposure levels that are safe for various periods of employment, including but not limited to exposure levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his work experience." Although NIOSH guidance, p. 20, states that: "exposures should be kept *below* a risk level of 1 in 10,000, *if practical* [emphasis added]" EPA adheres to the 1 in 10,000 benchmark for occupational scenarios during the Risk Evaluation stage for TSCA chemicals. It is important to note that $1x10^{-4}$ is not a bright line and EPA has discretion to make unreasonable risk determinations based on other benchmarks or factors as appropriate. EPA has consistently applied a cancer risk benchmark of $1x10^{-4}$ for assessment of occupational scenarios under TSCA. This is in contrast with cancer risk assessments for consumers or the general population, for which $1x10^{-6}$ is applied as a benchmark (Section **Error! Reference source not found.**). See Section 5.1.1.2 of the Risk

		Evaluation for additional information. Note that other precedents (*e.g.*, Office of Water; Office of Air) are the basis for cancer benchmarks to be used for risks to the general population, but EPA did not quantitatively evaluate such scenarios for 1-BP. EPA has considered susceptible subpopulations when evaluating these risks, as directed by TSCA. Specifically, EPA used the lower 95th confidence bound on the cancer slope, which accounts for variability and uncertainty in individuals' tumor responses, including susceptible subpopulations. Standard cancer benchmarks used by EPA and other regulatory agencies are an increased cancer risk above benchmarks ranging from 1 in 1,000,000 to 1 in 10,000 (*i.e.*, $1x10^{-6}$ to $1x10^{-4}$) depending on the subpopulation exposed.
Aggregate and Sentinel Exposure		
30, 34, 49, 53	**PUBLIC COMMENTS:** TSCA requires EPA to consider risks presented by all conditions of use, as well as risks from combinations of exposures across different pathways and routes of exposure. The draft risk evaluation only looks at inhalation and dermal routes separately but did not aggregate exposure from these two routes. The combined risk would be significantly larger than the risk for each pathway alone and the MOEs (Margin of exposure) would show an even greater likelihood of adverse developmental and reproductive effects. In addition, this would significantly increase the overall cancer risk relative to the EPA benchmark, raising the level of concern for carcinogenicity in the workplace.	EPA has determined that using the high-end risk estimate for inhalation and dermal risks separately as the basis for the unreasonable risk determination is a best available science. There is low confidence in the result of aggregating the dermal and inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk. TSCA Section 6(b)(4)(F)(ii) directs EPA to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration" in Risk Evaluations. EPA defines aggregate exposures as the combined exposures to an individual from a single chemical substance across multiple routes (*i.e.*, dermal, inhalation, or oral) and across multiple pathways (*i.e.*, exposure from different sources). 40 CFR 702.33. EPA defines sentinel exposures as the exposure from a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures. 40 CFR 702.33. EPA considered the reasonably

		available information and used the best available science to determine whether to consider aggregate or sentinel exposures for a particular chemical. EPA has determined that using the high-end risk estimate for inhalation and dermal risks separately as the basis for the unreasonable risk determination is a best available science. There is low confidence in the result of aggregating the dermal and inhalation risks for this chemical if EPA uses an additive approach, due to the uncertainty in the data. EPA does not have data that could be reliably modeled into the aggregate, which would be a more accurate approach than adding, such as through a PBPK model. Using an additive approach to aggregate risk in this case would result in an overestimate of risk.
47	**PUBLIC COMMENTS:** • EPA has not established that its "high-end" exposure assessment represents the "plausible upper bound of exposure relative to all other exposures" within the relevant categories.	In this Risk Evaluation, EPA considered sentinel exposure the highest exposures given the details of the conditions of use and the potential exposure scenarios. EPA considered sentinel exposures by considering risks to populations who may have upper bound (*e.g.*, high-end, high intensities of use) exposures.
Need for more transparency		
50	**PUBLIC COMMENTS:** • The 1-BP draft risk evaluation should describe any consultation or coordination with OSHA and other EPA program offices. In addition, the 1-BP risk evaluation describes EPA's coordination with the OAR regarding potential regulation of 1-BP as a Hazardous Air Pollutant (HAP); however, EPA should provide more information about how it determines whether existing regulations are adequate to address risks associated with the chemical under its conditions of use.	In the 2017 Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act (82 FR 33726, July 20, 2017), EPA committed to, by codifying, interagency collaboration to give the public confidence that EPA will work with other agencies to gain appropriate information on chemical substances. This is an ongoing deliberative process and EPA is not obligated to provide descriptions of pre-decisional and deliberative discussions or consultations with other federal agencies. In the interest of continuing to have open and candid discussions with our interagency partners, EPA is not intending to include the content of those discussions in the risk evaluation. As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources,

		avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1).
31	**PUBLIC COMMENTS:** • Draft risk assessment is largely biased toward using (1) mainly governmental sources to report physical, use and market data regarding 1-BP and (2) using older historical data that is not reflective of the nature of 1-BP use in the US currently. Current governmental and non-governmental data sources are reasonably available but do not appear to have been considered. • Also, exposure limit used to determine reasonable/unreasonable risk in the draft risk assessment is many times lower than the official USEPA workplace exposure level of 18 to 30 ppm regarding 1-BP for non-cancer endpoints in the 2007 final rule (72 FR 30142-30167). There is no discussion of the current USEPA official opinion and why any changes were considered necessary.	As noted in the document entitled *EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA*, EPA-HQ-OPPT-2016-0723-0067, EPA conducted extensive and varied data gathering activities for each of the first 10 chemicals, including: • Extensive and transparent searches of public databases and sources of scientific literature, government and industry sector or other reports; • Searches of EPA TSCA 8(e), Chemical Data Reporting, and other EPA information holdings; and CBI submission holdings; • Searches for Safety Data Sheets (SDSs) using the internet, EPA Chemical and Product Categories (CPCat) data, the National Institute for Health's (NIH) Household Product Database, and other resources in which SDS could be found; • Preparation of a market analysis using proprietary databases and repositories; • Outreach meetings with chemical manufacturers, processors, chemical users, non-governmental organizations, trade organizations, and other experts, including other State and Federal Agencies (*e.g.*, Dept of Defense, NASA, OSHA, NIOSH, FDA and CPSC); and • Publication of conditions of use documents, scope documents, and problem formulation documents to solicit information generally from industry, nongovernmental organizations, and the public. • The Final Risk Evaluation reflects reasonably available information as described above and uses more recent exposure and hazard data since the 2007 final rule to make reasonable/unreasonable risk determination.
27	**PUBLIC COMMENTS:** • Establishing a thorough and deliberate process is necessary as EPA conducts its first set of risk evaluations as part of the 2016 updates to TSCA. Providing only 18 days to comment on the draft evaluation, which is 406	EPA appreciates the comment and continues to look to ways to improve the risk evaluation process, such as adequate public comment timeframes.

	pages long and includes 16 supporting documents, may not give stakeholders enough time to thoroughly review it and provide comments. Having a longer period to review the draft would also provide SACC peer reviewers the opportunity to adequately review public comments.	
49	**PUBLIC COMMENTS:** • EPA should list 1-BP under section 5(b)(4) of TSCA as a chemical that "present[s] or may present an unreasonable risk to human health and the environment." This listing will increase the transparency of EPA's decision making, provide additional disclosure of exports of products containing 1-BP, and enhance awareness of the harmful effects of acute exposure.	EPA's Risk Evaluation of 1-BP is conducted under Section 6 of TSCA, which requires that any unreasonable risks be addressed by regulation under the authorities of Section 6. Any action under Section 5(b)(4) is separate from this process.
Recommendations to Improve the Risk Evaluation (Listed on pages 72-73):		
SACC	**SACC COMMENTS:** • 1-BP release or transport into groundwater. • There are several instances within the Environmental Assessment where the phrasing implies more rigor or confidence in data than is justified. For example, the 1-BP assessment should clearly and unambiguously state: a "lack of sediment and terrestrial toxicity test data creates significant uncertainty." The current language states "some uncertainty" (page 246). Lack of 1-BP data in soil and the lack of assessment presents a significant shortcoming in the assessment of environmental hazards, including a need to protect threatened or endangered species. As noted in response to charge question 4, the Committee questioned the assumption that little 1-BP will enter soil/subsurface. The Agency's assumption here is unlikely to be accurate. • The Agency should consider inclusion of exposure to other chemicals (at least 9 in drinking water) to deconvolute 1-BP exposure from other halocarbons. (page 69)	EPA considered the groundwater and sediment routes of exposure by examining reported releases to water and modeling of environmental fate. The systematic review of the 1-BP fate and transport literature included queries to capture information on 1-BP groundwater and sediment routes of exposure. However, no reasonably available information on 1-BP groundwater or sediment fate or monitoring values in sediment groundwater was identified. Instead, EPA considered the occurrence and magnitude of TRI reported environmental releases to water and land. Available TRI reporting for 1-BP releases to water have been consistently low with reported releases of 1-BP of 5 pounds (2016), 1 pound (2017), and 1 pound (2018). EPA incorporated predicted partitioning coefficients of 1-BP to aquatic sediment into the qualitative assessment of risk to sediment-dwelling organisms in the Final Risk Evaluation. Estimated screening level surface water concentrations resulting from TRI releases combined with estimated environmental partitioning using a Level III Fugacity model was used qualitatively to determine that 1-BP risk to sediment dwelling organisms is unlikely. The details are provided in Section 2.1 Fate and Transport, Section 3.1 Environmental Hazards, and Section 4.1 Environmental Risk.
	• Exposures to be aggregate and not separate (*e.g.*, vapor and dermal exposures are not separable).	As explained in the Final Risk Evaluation, EPA determined that aggregating dermal and inhalation exposure for risk characterization was not appropriate due to uncertainties in quantifying the relative

		contribution of dermal v. inhalation exposure to the total internal dose. Additional explanation is provided in Section 4.4.2 of the Risk Evaluation. While TSCA Section 6(b)(4)(F)(ii) does not require aggregation of exposures, EPA did consider aggregating dermal and inhalation exposures. The final publication of the Risk Evaluation has additional language to Section 4.4.2 regarding aggregating dermal and inhalation exposures. Aggregating exposures from multiple routes could inappropriately overestimate total exposure, as simply adding exposure from different routes without an available PBPK model for those routes, would compound uncertainties concerning the true internal dose.
Additional SACC Recommendations		
SACC	**SACC COMMENTS:** • The Committee found it difficult to follow the exclusion criteria that significantly winnowed available literature to a small percent of available studies that were utilized in the assessment. This translucency limits the Committee's ability to make a fully informed assessment of the objectivity used to retain/exclude data for the 1-BP assessment. The exclusion criteria produced no or quite limited data (n=2) for environmental exposures which cascaded into large uncertainties for environmental exposures. The Committee recommended adding a table similar to that depicted in Table 2: Proposed Summary Table Describing Scope of Risk Determination on page 73 of the SACC FINAL REPORT. (page 65)	EPA's systematic review and quality evaluation method was developed following identification and review of various published qualitative and quantitative scoring systems to inform our own fit-for-purpose tool. The development process involved reviewing various evaluation tools/frameworks (*e.g.*, OHAT Risk of Bias tool, CRED, etc.; see Appendix A of the *Application of Systematic Review in TSCA Risk Evaluations* document and references therein), as well as soliciting input from scientists based on their expert knowledge about evaluating various data/information sources specifically for risk assessment purposes. While EPA's systematic review process may differ from other procedures or guides, it was developed specifically for the TSCA Risk Evaluation process and included certain protocols and processes. Based on comments received and challenges experienced with EPA's process, for the first round of Risk Evaluations, EPA is revising it systematic review process for added transparency and clarity. Additionally, the revision process includes more detail, specificity, and data integration than previously applied as well as developing clearer, more transparent protocols and practices to be applied in future Risk Evaluation processes. The revised process is also going through a more intense peer review including through the National Academy of Sciences.
	• Provide information about BPMA. Many occupational	For the purpose of the 1-BP Risk Evaluation, EPA is not using BPMA

	exposure studies have consistently identified significant correlations between 1-BP inhalation and the concentrations of 1-BP or its metabolites in urine (Ichihara et al., 2004b; Kawai et al., 2001; Hanley et al., 2010, 2009; NIOSH, 2007). It is difficult to determine what fraction of BPMA in the general population results from 1-BP; however, given the reliance on procedures and data of other agencies to prepare this risk determination and given that NHANES accepts BPMA concentrations in urine as a surrogate 1-BP-exposure, it would seem prudent to use BPMA as a surrogate for exposure here. At the very least, the risk assessment document should contain references and chemical pathways, detailing how other compounds can metabolize into BPMA. It should also be noted, that if BPMA is a toxic metabolite of 1-BP, starting with baseline levels of BPMA, regardless of what chemical generates the metabolite, would increase the toxicity of 1-BP exposure. (page 68)	as a biomarker at this time. As noted by the SACC, BPMA is also a metabolite of several other compounds. The uncertainties associated of various biomarkers of exposure is discussed in Section 3.2.4 of the Risk Evaluation.

	• The Agency Should Pursue:
	  • Improved clarity in study inclusion/retention;
	  • A correct parameterization of the P_Der2b model representation;
	  • Additional data to define environmental aspects of the assessment;
	  • Weight data to study strength;
	  • A quantitative sensitivity analysis for exposure and effects data;
	  • Greater representative AFs (or UFs) than the "blanket" value of 10.
		EPA made the corrections associated with the incorrect identification of the P_Der2b model in the Final Risk Evaluation. EPA also revised input parameters to utilize neat-based parameters instead of the aqueous-based parameters.
		
		Additionally, EPA made a number of changes throughout the document to improve clarity of its assessment and the weight of evidence discussion.

Content and Organization		
Charge Question 8.1: Please comment on the overall content, organization, and presentation of the Draft Risk Evaluation of 1-BP. **Charge Question 8.2:** Please provide suggestions for improving the clarity of the information presented in the documents.		
#	**Summary of Peer Review Comments for Specific Issues Related to Charge Question 8**	**EPA/OPPT Response**
General comment about overall content		
SACC	**SACC COMMENTS:** • One Committee member appreciated the detailed discussion of uncertainty in the Consumer Exposure Section and recommended to use this approach throughout the document. • The use of hyperlinks throughout the text is potentially useful but in the risk assessment document the hyperlinks often led to a database where the document must then be searched if the proper reference is known. The hyperlinks would better be used to link directly to a bibliography where additional hyperlink would connect with the reference document.	EPA appreciates the feedback and has made several changes to the Final Risk Evaluation, where appropriate.
25	**PUBLIC COMMENTS:** • EPA should consider modeling the weight of evidence narratives for hazard endpoints (*e.g.*, developmental and reproductive toxicity) based on the WOE narrative developed for neurotoxicity, which succinctly characterizes the quality, reproducibility, uncertainties, and consistency of evidence, both within and across lines of evidence (human and animal).	Additional language was added to the Risk Evaluation for developmental and neurotoxicity hazard endpoints since these were the endpoints utilized for risk characterization and unreasonable risk determination. Additional edits were not made to other sections because there is relatively less reasonably available information for those endpoints and they were not the driver endpoints for risk estimation.
47	**PUBLIC COMMENTS:** • EPA's limited consideration of risks to children lacks transparency. In numerous places throughout the draft risk evaluation, it appears that EPA did not consider infants or children as vulnerable subpopulations for any industrial/commercial conditions of use.	EPA does not believe children and infants are typically exposed at the workplaces associated with industrial/commercial conditions of use. In addition, EPA has explained its consideration of children at dry cleaners in Section 2.
	• EPA failed to acknowledge that the requirements it relies on derive from statutes that establish criteria different than	Section 1.4.2 of the Risk Evaluation discusses certain Exposure Pathways and Risks Addressed by Other EPA-Administered Statutes.

	those under TSCA for establishing requirements to address human and environmental health risks.	
	• While defaults have their place, there is no excuse for EPA failing to even mention its authority to require the development and submission of the information it needs	EPA believes it had sufficient information to complete the 1-BP Risk Evaluation using a weight of scientific evidence approach. EPA selected the first 10 chemicals for Risk Evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development. When preparing this Risk Evaluation, EPA obtained and considered reasonably available information, defined as information that EPA possesses, or can reasonably obtain and synthesize for use in Risk Evaluations, considering the deadlines for completing the evaluation. Given the timeframe for conducting Risk Evaluations on the first 10 chemicals, use of TSCA data gathering authorities has been limited in scope. In general, EPA intends to utilize TSCA data gathering authorities more routinely for the next 20 Risk Evaluations.
Need for clarification		
SACC	**SACC COMMENTS:** • The 1-BP conceptual model presented in the DRE excludes some important reasonably anticipated exposure pathways, especially general population exposure from local indoor and outdoor air concentrations associated with consumer and industrial uses. If the EPA maintains the narrow focus of the current evaluation, the document should be explicit that these scenarios are out of scope in order to facilitate States to take action without running into preemption barriers. Specific scenarios that should be included are 1) chronic exposure to 1-BP by a child spending time in a family business such as a dry cleaner where 1-BP is used, 2) chronic exposure of a child at home to 1-BP in indoor air from storing and occasionally using consumer products, 3) chronic exposure of a child at home to 1-BP from 1-BP-containing insulation, 4) chronic exposure of a child at home from 1-BP in ambient air associated with emissions from a nearby dry cleaner or degreaser or other small industrial user, and 5) chronic	As explained in more detail in Section 1.4.2 of the Risk Evaluation, EPA believes it is both reasonable and prudent to tailor TSCA Risk Evaluations when other EPA offices have expertise and experience to address specific environmental media, rather than attempt to evaluate and regulate potential exposures and risks from those media under TSCA. EPA believes that coordinated action on exposure pathways and risks addressed by other EPA-administered statutes and regulatory programs is consistent with statutory text and legislative history, particularly as they pertain to TSCA's function as a "gap-filling" statute, and also furthers EPA aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing Risk Evaluations. EPA has therefore tailored the scope of the Risk Evaluation for 1-BP using authorities in TSCA Sections 6(b) and 9(b)(1). Since the problem formulation and release of Draft Risk Evaluation, EPA has issued a final notice to grant the petitions to add 1-BP to the HAP list under Section 112 of the CAA. 85 FR 36851 (June 18, 2020). This will trigger a regulatory process under the CAA.

	exposure in the home associated with groundwater contamination from spills or discharges and subsequent drinking water or vapor intrusion pathways.	EPA also added language to the Final Risk Evaluation discussing some broad requirements of Section 112 of the CAA addressing several concerns raised in these comments. In summary, the CAA contains a list of HAP and provides EPA authority to add to that list pollutants which present, or may present, adverse human health or environmental effects. The CAA requires issuance of technology-based standards for stationary (and area) sources to protect public health, welfare, and the environment. The CAA also requires residual risk review of technology-based standards and, if necessary, revisions to those technology-based standards to ensure adequate protection of public health, welfare, and the environment. Exposure to 1-BP by a child spending time in a family business such as a dry cleaner where 1-BP is used is discussed in Section 2.3.1. For this condition of use, MOE estimates for the developmental toxicity endpoint presented in Section 4 are expected to be protective of children potentially present at dry cleaners. Due to the high volatility of 1-BP and a short residence within a residence following use of a consumer product, EPA does not expect exposure to consumers to be chronic in nature (with the exception of the insulation (off-gassing) condition of use, which has been revised to consider chronic exposure). Consumer exposure (including child exposure) to 1-BP due to off-gassing from 1-BP containing insulation (rigid board insulation) is indirectly evaluated through the revisions to the insulation (off-gassing) condition of use. Consumer exposure for this specific condition of use was revised to include acute non-cancer, chronic non-cancer, and cancer exposures. It was also expanded to consider two building configurations including a full basement where a child may spend time playing if the basement is finished. Consumer exposure (including child exposure) to 1-BP due to storage of consumer products is difficult to link to a given condition of use and is not itself an identified consumer condition of use and therefore was not considered in scope for this Risk Evaluation. Additionally, TSCA Section 6(b)(4)(F)(iv) instructs EPA to factor into TSCA Risk

		Evaluations "the likely duration, intensity, frequency, and number of exposures under the conditions of use." This suggests that activities for which duration, intensity, frequency, and number of exposures cannot be accurately predicted or calculated based on reasonably available information were not intended to be the focus of TSCA Risk Evaluation. Since reasonably available information was not identified to inform these and other parameters (including off-gassing rates or concentrations) and as recognized by SACC that the absence of data leaves it uncertain how to develop a worst-case scenario, storage of consumer products was not evaluated in this Risk Evaluation. Spills and leaks generally are not included within the scope of a TSCA Risk Evaluation. EPA is exercising its authority under TSCA to tailor the scope of the Risk Evaluation for 1-BP, rather than evaluating activities which are determined not to be circumstances under which 1-BP is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, or environmental exposure pathways addressed by another EPA-administered statute and associated regulatory program. First, EPA does not identify 1-BP spills or leaks as "conditions of use." EPA does not consider 1-BP spills or leaks to constitute circumstances under which 1-BP is manufactured, processed, distributed, used, or disposed of, within TSCA's definition of "conditions of use." Congress specifically listed discrete, routine chemical lifecycle stages within the statutory definition of "conditions of use" and EPA does not believe it is reasonable to interpret "circumstances" under which 1-BP is manufactured, processed, distributed, used, or disposed of to include uncommon and unconfined spills or leaks for purposes of the statutory definition. Further, EPA does not generally consider spills and leaks to constitute "disposal" of a chemical for purposes of identifying a COU in the conduct of a Risk Evaluation. In addition, even if spills or leaks of 1-BP could be considered part of the listed lifecycle stages of 1-BP, EPA has "determined" that spills and leaks are not circumstances under which 1-BP is intended, known or reasonably foreseen to be manufactured, processed, distributed,

		used, or disposed of, as provided by TSCA's definition of "conditions of use," and EPA is therefore exercising its discretionary authority under TSCA Section 3(4) to exclude 1-BP spills and leaks from the scope of the 1-BP Risk Evaluation. The exercise of that authority is informed by EPA's experience in developing scoping documents and risk evaluations, and on various TSCA provisions indicating the intent for EPA to have some discretion on how best to address the demands associated with implementation of the full TSCA risk evaluation process. Specifically, since the publication of the Risk Evaluation Rule, EPA has gained experience by conducting ten risk evaluations and designating forty chemical substances as low- and high-priority substances. These processes have required EPA to determine whether the case-specific facts and the reasonably available information justify identifying a particular activity as a "condition of use." With the experience EPA has gained, it is better situated to discern circumstances that are appropriately considered to be outside the bounds of "circumstances… under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" and to thereby meaningfully limit circumstances subject to evaluation. Because of the expansive and potentially boundless impacts that could result from including spills and leaks as part of the Risk Evaluation, which could make the conduct of the Risk Evaluation untenable within the applicable deadlines, spills and leaks are determined not to be circumstances under which 1-BP is intended, known or reasonably foreseen to be manufactured, processed, distributed, used, or disposed of, as provided by TSCA's definition of "conditions of use." Exercising the discretion to not identify spills and leaks of 1-BP as a COU is consistent with the discretion Congress provided in a variety of provisions to manage the challenges presented in implementing TSCA Risk Evaluation. See *e.g.*, TSCA Sections 3(4), 3(12), 6(b)(4)(D), 6(b)(4)(F). In particular, TSCA Section 6(b)(4)(F)(iv) instructs EPA to factor into TSCA Risk Evaluations "the likely duration, intensity, frequency, and number of exposures under the conditions of use….," suggesting that activities for which duration, intensity, frequency, and number of exposures cannot be accurately predicted or calculated

		based on reasonably available information, including spills and leaks, were not intended to be the focus of TSCA Risk Evaluations. And, as noted in the preamble to the Risk Evaluation Rule, EPA believes that Congress intended there to be some reasonable limitation on TSCA Risk Evaluations, expressly indicated by the direction in TSCA Section 2(c) to "carry out [TSCA] in a reasonable and prudent manner." For these reasons, EPA is exercising this discretion to not consider spills and leaks of 1-BP to be COUs. Second, even if 1-BP spills or leaks could be identified as exposures from a COU in some cases, these are generally not forms of exposure that EPA expects to consider in risk evaluation. TSCA Section 6(b)(4)(D) requires EPA, in developing the scope of a Risk Evaluation, to identify the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations the Agency "expects to consider" in a Risk Evaluation. As EPA explained in the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" ("Risk Evaluation Rule"), EPA may, on a case-by-case basis, tailor the scope of the risk evaluation "in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination." 82 FR 33726, 33729 (July 20, 2017). In the Problem Formulation documents for many of the first 10 chemicals undergoing Risk Evaluation, EPA applied the same authority and rationale to certain exposure pathways, explaining that "EPA is planning to exercise its discretion under TSCA 6(b)(4)(D) to focus its analytical efforts on exposures that are likely to present the greatest concern and consequently merit a risk evaluation under TSCA...." The approach discussed in the Risk Evaluation Rule and applied in the Problem Formulation documents is informed by the legislative history of the amended TSCA, which supports the Agency's exercise of discretion to focus the Risk Evaluation on areas that raise the greatest potential for risk. See June 7, 2016 Cong. Rec., S3519-S3520. In addition to TSCA Section 6(b)(4)(D), the Agency also has

		discretionary authority under the first sentence of TSCA Section 9(b)(1) to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered in whole or in part by the Administrator." TSCA Section 9(b)(1) provides EPA authority to coordinate actions with other EPA offices, including coordination on tailoring the scope of TSCA Risk Evaluations to focus on areas of greatest concern rather than exposure pathways addressed by other EPA-administered statutes and regulatory programs, which does not involve a risk determination or public interest finding under TSCA Section 9(b)(2). Following coordination with EPA's Office of Land and Emergency Management (OLEM), EPA has found that exposures of 1-BP from spills and leaks fall under the jurisdiction of RCRA. Solid wastes containing 1-BP may be regulated as a hazardous waste under the RCRA waste code D001 (ignitable liquids, 40 CFR 261.21(a)(1)). As a result, EPA believes it is both reasonable and prudent to tailor the TSCA Risk Evaluation for 1-BP by declining to evaluate potential exposures from spills and leaks, rather than attempt to evaluate and regulate potential exposures from spills and leaks under TSCA.
SACC	• Specific Comments Regarding Clarity to be Addressed (Listed on page 82-83): ○ Typographical errors are present in the document and it requires careful editing. ○ Although the descriptions of the Weight of Evidence (WoE) considerations for non-cancer hazard endpoints seem logical, the actual WoE process is unclear, *e.g.*, what the weighting system is and how each data point was assessed and the result of that assessment (the data quality evaluation column in Table Appendix I-2 is not that informative). Perhaps a second table showing the WoE analysis for each endpoint within the endpoints chosen would be helpful in supporting the choice of specific studies and specific endpoints for Point of Departure selection. ○ Section 1.3 page 31 would be more useful if there	EPA appreciates the recommendations. In finalizing the Risk Evaluation, EPA incorporated a number of corrections, editorial changes, and formatting changes throughout the document to improve flow and clarity, in consideration of the comments received. For example, reference to the Appendix F table (formerly Appendix E) in the Risk Evaluation has been corrected. Data presentation has been revised to correctly present significant figures and scientific notation (where appropriate) in the Final Risk Evaluation. Table 5.1 no longer references numerical values in the Final Risk Evaluation. The Executive Summary has also been revised for better readability.

	were a summary in the text and not just directions to the appendix. ○ Table 2-39 page 104 is a good addition. ○ Section 4.3 page 239, it would be clearer if all the assumptions made in the risk assessment were included in one titled section rather than integrated throughout the document. The Committee discussed including the assumptions with the hazard and risk sections and the main drivers in one location. ○ Appendix E consists of a table summarizing 27 different iterations for consumer uses. It states that this table is repeated in §2-43, but it is repeated in §2-44. ○ *Re Clarity in expression.* Confusing scientific notation is provided where it is not needed (*e.g.,* Table 2-59 and other tables). In addition, a mix of notations are used in Table 5-1. 4.52E+00 should be 4.52. 3.28E+01 should be 32.8. Due attention to consistent use of scientific notation and expression of significant figures in quantities is required. ○ *Consistency is usage of exponents and notation.* For example, (on page 141) use the same units and exponents, if needed, for comparisons purposes in the following text: "Therefore, the acute COCs for 1-BP ranged from 13,640-4,860 ppb (LC50 (24.3 mg/L) / AF of 5 = 4.86 mg/L or 4,860 µg/L or ppb; LC50 (67.3 mg/L) / AF of 5 = 13,640 µg/L or ppb). Based on estimated chronic hazard endpoints for fish, chronic COCs of 673-243 ppb were calculated (fish 96-hr LC50 (67.3 mg/L) / 10 (ACR) / AF of 10 = 673 µg/L or ppb; fish 96-hr LC50 (24.3 mg/L) / 10 (ACR) / AF of 10 = 0.243 mg/L or 243 µg/L or ppb)." ○ *Consolidation required.* For human health hazard the WOE discussion is mostly a rehash of the hazard discussion and could be combined into one section. ○ Tables 4-4 & 4-5 pages 189-191. It was clear which groups were examined for which COUs, (acute and chronic). Tables 4-4 and 4-5 were good examples to	

	follow. ○ It is difficult to align the text in the executive summary, with information presented in tables in §4 and Table 5-1. The Committee recommended that another table format be used that is simpler and clear.	
SACC	○ *Use of color to highlight information in tables.* Besides issues of inclusivity since a significant number of people are color-blind, so too are most computer printers. Alternative approaches should be sought to highlight differences in a table.	EPA has reviewed the Risk Evaluation and the table format and shading is consistent with the Agency's current accessibility guidelines and best practices.
SACC	○ It is unclear why Enviro Tech is noted within body of Section 2.3.1.8 page 64 but is not included in Table 2-12 page 65. Please ensure accuracy and completeness.	EPA has reviewed the comment and verified that the existing table is consistent with CDR data as reported to the Agency.
SACC	○ *Cross referencing error.* Human Health Hazard-Places where Appendix H used, and it should be Appendix I. ○ Page161 at the beginning of Section 3.2.8.2, there are some numbers in the middle of text. Also, the same errors in the middle of page 165. ○ Footnote on page 59 "Nitrile" is misspelled.	These editorial errors have been corrected in the Final Risk Evaluation.
SACC	○ Table 5-1 is difficult to read. The text states the EPA identifies a single human health adverse effect as the unreasonable risk driver, yet the table lists multiple drivers. The numbers for non-cancer or cancer for workers often look like there is risk, but the document states there is not unreasonable risk with personal protection equipment and refers the reader to a different number in another table on a different page, which is confusing. In some instances, it is not clear if the non-cancer risk driver was acute or chronic. There must be a better way to communicate the risk on this topic that contains less legal jargon and follows the wording of TSCA. ○ One Committee member suggested a change of the following language, which appears in multiple locations (*e.g.*, page 260 of the DRE), from: "There is no unreasonable risk when PPE (APF=10) is used." To	EPA appreciates the recommendation and has developed a revised Section 5 to clarify the basis for the unreasonable risk determination. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumes use of PPE, what APF or PF is assumed, and how the risk estimates support or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk. In light of SACC recommendation on the occupational dermal exposure model, EPA has revised the experimental fraction absorbed (f_{abs}) value from Frasch et al. (2011) to account for the effect of wind speed. EPA's analysis is included in Appendix E of the Final Risk Evaluation.

	"There is no unreasonable risk when PPE is used in a manner that achieves an effective APF of 10." This change would remove the implication that EPA assumes that use of PPE is universally effective. Overall, while inclusion of dermal exposure is an improvement over the prior analysis reviewed by CSAC (which considered only inhalation risk), treatment of dermal exposure in the draft RE is technically defective. The consumer dermal exposure uses an incorrect model. The occupational dermal exposure assessment may underestimate dermal absorption from liquid product due to uncritical review of and selective use of data from Frasch et al. (2011) and because it ignores potential direct uptake from vapor altogether. Therefore, further improvement is necessary before the DRE is finalized.	EPA's approach for developing exposure assessments for workers is to use the reasonably available information. When appropriate, in the Risk Evaluation, EPA will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. For the purposes of determining whether a condition of use presents unreasonable risks, EPA incorporates assumptions regarding PPE use based on information and judgement underlying the exposure scenarios. These assumptions are described in the unreasonable risk determination for each condition of use, in Section 5.2. Additionally, in consideration of the uncertainties and variabilities in PPE usage (*e.g.*, dry cleaners), including the duration of PPE usage, EPA uses the high-end exposure value when making its unreasonable risk determination in order to address those uncertainties.
50	**PUBLIC COMMENTS:** • TSCA Risk Evaluations should employ a consistent format and make clearer how EPA's risk characterization supports its risk determinations. In particular, the unreasonable risk determination (Table 6.1) needs EPA's close attention -- the table is not organized in an easily understandable way and needs citing to certain sections in the risk characterization which point to supporting evidence and note endpoints which exceed benchmarks.	The Final Risk Evaluation includes an additional subsection to better summarize results of EPA's risk characterization (see Section 4.5: Risk Conclusions). In addition, the structure and format of the Unreasonable Risk Determination (Section 5) has been updated to improve readability of the information. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumed sue of PPE, what APF or PF is assumed, and how the risk estimates support or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk.
25	**PUBLIC COMMENTS:** • EPA's consideration of personal protective equipment (PPE) in Table 5-1 (Risk Determination by Conditions of Use) is confusing. It is unclear whether workers are being protected with PPE. • Risk communication in the risk determination, Section 5.2, needs 1) editing for consistency and clarity, 2) citations in Table 5-1, 3) citations to the relevant supporting scientific information for each decision made	EPA appreciates the recommendation and has developed a revised Section 5 to clarify the basis for the unreasonable risk determination. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumes use of PPE, what APF or PF is assumed, and how the risk estimates support or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk.

	under the risk determination section, 4) expanded to include a separate paragraph for "workers"	
38	**PUBLIC COMMENTS:** • The risk determination section for 1-BP could use further streamlining and clarification. Given that this document is a draft, and EPA has the opportunity to further edit the document, based on feedback from peer reviewers and stakeholder comments. However, as commented on the previous risk evaluations, the risk determination sections of the risk evaluations are critically important for communication to the public. Therefore, EPA should give particular attention to the final risk determination sections and should seek to clarify the basis for the determinations and better summarize and highlight the overall determinations in order to improve the public's understanding of them.	EPA has developed a revised Section 5 to clarify the basis for the unreasonable risk determination. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumes use of PPE, what APF or PF is assumed, and how the risk estimates support or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk.
45	**PUBLIC COMMENTS:** • This comment was limited to EPA's reference to, and characterization of typical uses for, polyisocyanurate insulation. The Polyisocyanurate Insulation Manufacturers Association (PIMA) members produce the majority of polyisocyanurate insulation manufactured and sold in the United States, and do not use 1-BP in their respective product formulations. The term "polyisocyanurate insulation" throughout the risk evaluation creates the risk for marketplace confusion that all polyisocyanurate insulation products contain 1-BP. PIMA respectfully requests that EPA use the terms "THERMAX" or "THERMAX polyisocyanurate" when discussing the insulation end-use that is the subject of the risk evaluation.	EPA appreciates the comment. In the Final Risk Evaluation, EPA has provided additional information regarding the insulation use of 1-BP in rigid insulation, re-calculated risk estimates and has issued a revised unreasonable risk determination for use of 1-BP in insulation.
47	**PUBLIC COMMENTS:** • EPA's presentation of its risk determinations in Table 5-1 (pp. 260-289) dramatically understates the extent of actual unreasonable risk it has identified.	EPA has developed a revised Section 5 to clarify the basis for the risk determination and present the unreasonable risk identified. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumes use of PPE, what APF or PF is assumed, and how the risk estimates support

		or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk.
Comments about 1-BP uses		
SACC	**SACC COMMENTS:** • One Committee member composed a summary table to be used in conjunction with the information compiled into Table 5-1: Unreasonable Risk Determination page 260 of the DRE. This summary is presented in Table 5 of the SACC FINAL REPORT (page 82) and is a summary of 1-BP life cycle, uses, exposure pathways and expected impacts on humans	EPA appreciates the recommendation and has developed a revised Section 5 to clarify the basis for the unreasonable risk determination. The details of the considerations in the unreasonable risk determinations for each condition of use now more clearly state when EPA assumes use of PPE, what APF or PF is assumed, and how the risk estimates support or do not support a determination of unreasonable risk for that condition of use. EPA also describes the other factors considered when making determinations of unreasonable risk.
27	**PUBLIC COMMENTS:** • Halogenated solvents are used in industrial and commercial settings because they are essentially non-flammable and reduce the overall fire risk. A significant need exists in the marketplace for cleaning solvents with the wide solubility parameters and excellent cleaning capabilities of 1-BP. Limiting solvent choices could result in an abrupt and significant change for industrial and commercial facilities that are designed to handle materials rated as non-flammable. • A condition of use that has not been adequately evaluated by EPA is processing of 1-BP for use as a recyclable reaction solvent. It should be listed as a "reaction solvent" under "processing – incorporating into formulation, mixture or reaction product" as described in Table 1-4.	TSCA requires that a Risk Evaluation not consider "cost or other non-risk factors" such as need in the marketplace. During the risk management phase, EPA may consider whether substitutes are reasonably available when deciding on regulatory actions, as required by TSCA Section 6(c). After a discussion with the commenter, EPA determined that processing of 1-BP as "recyclable reaction solvent" was not a condition of use of 1-BP under TSCA.
Additional SACC Recommendations		
SACC	**SACC COMMENTS:** • As written, the Committee considers the Executive Summary to be too long, confusing in spots, and consisting of too many acronyms. For example, the paragraph on the first page on the main use and other conditions of use implied a very small list of COUs, but then there was the long list of COUs on the next page.	EPA has reorganized the Executive Summary based on SACC feedback according to the format used by subsequent Draft Risk Evaluations.

	• The Committee recommended that an additional summary in lay language be included with the Executive Summary. Greater effort to explain the risk assessment document will help foster better communication with the public and help gain its trust. • Refer to SACC FINAL REPORT (pages 75-81) for a description of an Adverse Outcomes Pathways (AOPs) conceptual modeling approach that can be used to understanding 1-BP effects/hazards and convey large sets of information to a reader. • Use OPPT Technical Presentation on 1-BP from peer review panel meeting as template for executive summary. The oral presentation made by the EPA was clear and well organized. (page 74)	