

Summary of Public Comments Received on the Draft Scopes of the Risk Evaluations for Twenty Chemical Substances Under the Toxic Substances Control Act (TSCA)

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In this document, the U.S. Environmental Protection Agency (EPA) is responding to overarching, cross-cutting policy and process comments, as well as chemical-specific comments received during the public comment periods following announcement of draft scopes of the risk evaluations for 20 chemical substances designated as High-Priority Substances for risk evaluation under the Toxic Substances Control Act (TSCA).

Comments were received during two 45-day public comment periods following the announcement of the draft scope documents for the risk evaluations to be conducted for 13 of 20 High-Priority Substances under TSCA (85 FR 19941 (April 9, 2020)) and the remaining 7 of 20 High-Priority Substances under TSCA (85 FR 22733 (April 23, 2020)). During both comment periods, the public was invited to submit comments on EPA's draft scope documents, including additional data or information relevant to the chemical substances or that otherwise could be useful to the Agency in finalizing the scope of the risk evaluations. To the extent that comments provided information on conditions of use, as well as other elements of the draft scope documents, those comments and other submitted information (e.g., relevant studies and assessments) were used to inform revisions to the draft scope documents and may be considered in subsequent phases of the risk evaluation process.

EPA created one general docket to receive comments regarding the risk evaluation process and additional, individual dockets on each of the 20 High-Priority Substances undergoing risk evaluation to receive chemical-specific information. From all 21 dockets, EPA received 245 submissions; however, some commenters opted for one submission describing all their comments and submitted it to multiple dockets, other commenters chose to submit different comments to individual chemical-specific dockets, and some commenters did both. Therefore, EPA considered 78 of those submissions unique. For those submissions in multiple dockets that were identical or very similar, only one docket is referenced in the summary below. EPA received submissions from 66 different entities, including potentially affected businesses or trade associations, environmental and public health advocacy groups and academia (including some submissions signed by more than one group), a group of state attorneys general, and other organizations.

Comments addressed the overall risk evaluation process (e.g., the overall approach to the scope documents and risk evaluation process, including collection, consideration, and systematic review of relevant information), the specific elements of the scope documents (e.g., hazard, exposure, and potentially exposed or susceptible subpopulations (PESS)), information specific to the candidate chemical substances (e.g., relevant studies, assessments, conditions of use (COUs), and confidential business information (CBI)), and topics beyond the draft scope document phase of the process (e.g., risk management). One comment (EPA-HQ-2018-0465-0028) was not related to the risk evaluation of the 20 High-Priority Substances.

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Overall Risk Evaluation Process

Approach to Scope Documents

Comment: Several commenters (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0040, EPA-HQ-OPPT-2019-0131-0041, EPA-HQ-OPPT-2019-0131-0047, EPA-HQ-OPPT-2018-0421-0022) called on the Agency to address concerns in the draft scope documents that would amount to redrafting the existing draft scope documents and the publication and request for public comment on revised scope documents. One of the commenters (EPA-HQ-OPPT-2019-0131-0041) cited TSCA section 6(b)(4)(D) and 40 CFR 702.41 and questioned whether EPA had met the fundamental requirements of the scoping exercise for any of the scope documents. The same commenter asserted that EPA “only generally described some broad categories of hazards, exposures, and potentially exposed or susceptible

subpopulations, and has suggested it will identify the specific hazards, exposures, and subpopulations – and the reasonably available information it relies on to identify them – only later, well after the current comment periods have closed and possibly even after the scopes are finalized.” The same commenter then used the draft scope document for formaldehyde (“Draft Scope of the Risk Evaluation for Formaldehyde (CASRN 50-00-0),” April 2020, EPA-HQ-2018-0438-0029) to support claims that the Agency failed to “co-release the systematic review document to be used to identify required scope elements” and “provide all reasonably available information used to identify required scope elements.”

Comment: Another commenter (EPA-HQ-OPPT-2019-0131-0040) echoed concerns on the completeness of information provided in the draft scope documents related to hazards and occupational exposures and stated “EPA thus concedes that the published drafts do not fully identify the chemical’s hazards, as required by TSCA, or describe the reasonably available information that EPA plans to consider in its risk evaluation, as required by EPA’s regulations” and that “the purpose of TSCA’s extensive prioritization and scoping process is to identify specific hazards that are associated with the chemical before the publication of a draft scope, so the public can comment on and identify gaps in EPA’s understanding of the chemical during the scoping process.”

Comment: Another commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) cited TSCA section 26(h) text to assert that “when making a decision based on science, [EPA is required to] use information, procedures, methodologies, and protocols consistent with the best available science” and to consider “the degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented.” The commenter asserted that “[t]he overly general and vague nature of EPA’s draft scopes clearly do not meet any reasonable test for clarity and completeness, and hence do not constitute a basis for making decisions based on science that utilize the best available science.” The commenter also cited 40 CFR 702.41(d) and (e), which apply to the hazard assessment and exposure assessment portions of a risk evaluation, as well 40 CFR 702.41(c)(7), to assert that “[f]or the risk evaluation to meet these requirements . . . [the] level of specificity needs to be present in the draft scope EPA makes available for public comment, not just in the final scope.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039) requested that EPA publish, either in the final scopes or in a supplement, specific sources, data points and assumptions EPA will rely on to evaluate each condition of use, as well as a list of excluded studies with detailed rationale for exclusion specific to each study with a description of relevant data contained therein, as it relates to each relevant condition of use. The same commenter requested that EPA establish an additional comment period to allow comment on EPA’s identification of data sources for each condition of use and related analysis, as published in either the final scopes or a supplement. Another commenter (EPA-HQ-OPPT-2018-0421-0026) raised concerns regarding EPA’s systematic review process, in particular excluded data sources.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049) recommended that EPA improve the overall organization and consistency of the scope documents to highlight the most important information. The commenter also requested greater clarity and specifics regarding the sources of information and stated “[i]t is particularly important that stakeholders have a clear understanding of the specific type of information EPA is using to inform the scope of the risk evaluations.” The commenter also suggested that gray literature (i.e., cited in Annex A) be included in a bibliography of the specific sources it is considering using in the risk evaluation, and that, for information on existing regulations (i.e., contained in Appendix D), referencing such information in the

text would “help the reader better understand how the existing regulatory landscape for a chemical impacts the scope of the risk evaluation.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) urged EPA to address “deficiencies in the first 10 [risk] evaluations” and that the “scoping process is the right time to outline these improvements and engage the public.” The commenter raised concerns about issues relating to the first 10 risk evaluations and expressed an interest that the scopes for the next 20 risk evaluations take a different approach.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0046) asserted “With a fast approaching statutory deadline, EPA published the Draft Scopes without key elements and without providing the opportunity for meaningful public review and comment. The defects in EPA’s Draft Scopes must be remedied now or the agency’s 5-year long TSCA safety evaluations of the 20 high-priority chemical substances will be compromised as the reliability of the evaluations hinge on the formulation of comprehensive scopes that fully comply with the governing law.” The commenter cited language in the draft scope documents describing future steps that EPA would take to enhance the risk evaluation process and stated “each of the Draft Scopes fail to satisfy the substantive requirements of TSCA and the EPA implementing regulations for these risk evaluations, including identifying the hazards, exposures, conditions of use, the potentially exposed or susceptible subpopulations, and the information and scientific approaches that EPA plans to use in the risk evaluation. *See* 15 U.S.C. § 2605(b)(4)(D); 40 C.F.R. § 702.41(c). Instead of publishing satisfactory Draft Scopes, EPA admits the inadequacies of the Draft Scopes and asserts that the missing information will be included in forthcoming systematic review documentation and other supplemental documents. By failing to provide the required information with the issuance of the Draft Scopes, EPA violates TSCA and the EPA implementing regulations and deprives the public of the opportunity to provide a full and meaningful review and comment on the Draft Scopes for each of the seven chemical substances. *See* 40 C.F.R. § 702.41(c)(7)(iii).”

Comment: A commenter (EPA-HQ-OPPT-2018-0421-0026) stated “EPA has failed to publish a sufficiently detailed ‘analysis plan’ in the Draft Scopes, despite explicitly stating that it would.” Another commenter (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049) stated EPA’s “Analysis plans could use more chemical-specific information, and general information should be included in a more generic approach document.” The same commenter continued “The draft scope documents are non-specific on the hazard endpoints that will be the focus of the risk evaluation. The draft scope documents largely describe general hazard endpoints that ordinarily would be included in a screening assessment. However, EPA should have gathered and obtained hazard information during the prioritization process.”

Comment: A commenter (EPA-HQ-OPPT-2018-0421-0027) urged EPA to revise the draft scope for 1,2-dichloroethane (EDC) to provide additional detail on: (1) specific hazards anticipated to be of particular relevance based on an initial review of the literature, and if possible, provide questions it aims to address in the draft risk evaluation; (2) how it intends to use existing agency reviews (e.g., Integrated Risk Information System (IRIS)) relative to *de novo* analyses, in developing health benchmarks; and (3) scoping and problem formulation information in the systematic review document or in a second draft scope. The commenter also requested that EPA refer to the recommendations provided in existing systematic review documents and ensure that the systematic review document for 1,2-dichloroethane and any revisions to the draft scope are accompanied by sufficient time for public comment (ideally 45 to 60 days) before the Agency commences preparation of the draft risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0031) stated “the draft scoping document includes few details and little information specific to di-ethylhexyl phthalate - (1,2-Benzene-dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester) (DEHP) and the overall plan for its risk evaluation. This lack of specificity makes it difficult to comment on all but the most obvious issues. It is also unclear how the EPA’s systematic review will consider previous assessment efforts and how the current evaluation will differ.”

Response: EPA appreciates the comments regarding ways to improve the risk evaluation process and continues to implement the requirements of the “Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act” (Risk Evaluation Rule) (40 CFR Part 702). As stated in the preamble to that rule “EPA’s overall objective of this rule is to ensure that it is able to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole, and that it always includes an evaluation of the conditions of use that raise greatest potential for risk. EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines. These same principles will also serve to guide EPA’s implementation of the procedures” (82 FR 33726, 33728 (July 20, 2017)).

In this regard, the Agency disagrees with the views that its current approach to publishing and receiving public comment on the draft scope documents is flawed and notes that each scope provides specific information on how the Agency fulfilled elements required by TSCA section 6(b)(4)(D) and 40 CFR 702.41. In accordance with 40 CFR 702.41(c), each draft scope document and final scope document includes the following information: the conditions of use that EPA plans to consider during risk evaluation; the potentially exposed or susceptible subpopulations, hazards and exposures that EPA plans to evaluate; a description of the reasonably available information and science approaches EPA plans to use; and a conceptual model, analysis plan, and plan for peer review for each chemical substance. Please note that elements of the above comments (e.g., hazard, exposure, and PESS) are addressed in appropriate sections elsewhere in this document.

In regard to science-based decision-making, the identification of hazards, exposures, COUs, and PESS that EPA expects to consider in each risk evaluation is consistent with requirements of TSCA sections 26(h) and (i), as well as 40 CFR 702.41 and involved consideration of reasonably available information in accordance with TSCA section 26(k) and 40 CFR 702.41 within the time period allotted by the statute. The scope documents describe how EPA considered reasonably available information, including relevant information, procedures, methodologies, and protocols, as well as applicable statutory and regulatory requirements and criteria, and how information sources used are relevant to the applicable criteria and considerations. The documents also include citations for all references used in the literature review of each of these chemical substances and links to those references that are publicly available. Finally, regarding comments on potential for understatement of exposure and risk, EPA does not characterize exposure or risk in the scope documents since this follows data quality review and evidence integration performed during the risk evaluation.

In regard to reasonably available information, the draft scope documents include a description of such reasonably available information, including relevant information in databases containing publicly available, peer-reviewed literature and gray literature (i.e., the broad category of data/information sources not found in standard, peer-reviewed literature databases), and data and information submitted under TSCA sections 4, 5, 8(e), and 8(d), as well as “for your information” (FYI) submissions. In addition, EPA sought public comment on each draft scope document and considered information

submitted by commenters or otherwise identified following publication of the draft scope documents, as appropriate, in developing the scope documents.

EPA is using the systematic review process described in the [Application of Systematic Review in TSCA Risk Evaluations](#) document to guide the process of searching for and screening reasonably available information, including information already in EPA's possession, for use and inclusion in the risk evaluation. For the scoping stage of risk evaluation, EPA applied these systematic review methods to reasonably available information regarding hazards, exposures, PESS, and conditions of use for each High-Priority Substance. During the searching and screening phase of systematic review, EPA considered, among other factors, the extent to which the information was reasonable for and consistent with the identification of hazards, exposures, PESS, and conditions of use that EPA plans to evaluate for each High-Priority Substance; and the extent to which the information was relevant for use in those scoping efforts. Accordingly, the analysis plans for each scope document reflect the plan for evaluation based on the level of systematic review completed to this point. The extent of clarity, completeness, variability, and uncertainty in the information will be determined during the data evaluation, synthesis, and integration stages. Through this process, EPA identified and refined the hazards, exposures, PESS, and conditions of use that EPA plans to evaluate for each High-Priority Substance. Populations, Exposures, Comparators, Outcomes (PECO) statements and search strings are included in Appendix A of each scope. As explained in the preamble to EPA's Risk Evaluation Rule (82 FR 33726 (July 20, 2017)), "EPA sees weight of the scientific evidence approach as an interrelated part of systematic review, and further believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA."

In the draft scope documents, EPA also acknowledged additional steps to be taken to finalize the scope documents and to complete the risk evaluation process. Based on consideration of public comments on draft scope documents, EPA described in each final scope document the specific ways in which elements of the scope were modified or new information was incorporated. For example, EPA has clarified when certain pathways fall under the jurisdiction of other EPA-administered statutes and associated regulatory programs. EPA also highlighted information on reasonably available information, conditions of use, hazards, exposures, analysis plan, conceptual model, and peer review in the Executive Summary of each scope document. As such, the Agency will not publish the revised scopes for an additional public comment period.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) encouraged EPA to make "early safe use determinations when data and information demonstrates that there is no unreasonable risk. Where the agency has data and information to support a determination that a particular use of a high priority chemical substance does not present an unreasonable risk, we recommend that the agency announce the safety determination early in the risk evaluation process."

Response: EPA will conduct risk evaluations in a fit-for-purpose manner. This approach is described in 40 CFR 702.41(a)(6), which states "The extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment." In addition, the Risk Evaluation Rule (82 FR 33726 (July 20, 2017)), explains that EPA may refine its evaluations for conditions of use, taking into account whether information and analysis are sufficient to make a risk determination using assumptions, uncertainty factors, and models or screening methodologies. In some cases, EPA may decide to expedite risk determinations for individual conditions of use. The Risk Evaluation Rule (82 FR 33726 (July 20, 2017)), preamble states that "at any point after EPA has issued its final scope

document, in cases where EPA has sufficient information to determine whether or not the chemical substance presents an unreasonable risk under particular conditions of use, the Agency may issue an early determination for that subset of conditions of use, while EPA continues to evaluate the remaining conditions of use. All early determinations would be portions of the final, complete risk evaluation and would therefore be made using the procedures applicable to TSCA risk evaluations established in this rule. This would include the requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period, and the regulatory requirement for peer review.” The issuance of any early risk determination will therefore be case-specific and will depend on the information that is reasonably available to EPA; the ability to assess the risk in a fit-for-purpose manner; and other relevant considerations.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) urged EPA to focus on best available science and conduct weight of evidence in a clear and transparent manner, including the review of information from other authoritative sources such as related to exposure to 1,3-butadiene via the ingestion of food and drinking water. The same commenter disagreed with EPA’s determination that a potential exposure pathway exists from release of 1,3-butadiene via publicly owned treatment works to surface water and subsequent partitioning to sediment and bioaccumulation into edible aquatic species.

Response: EPA will use reasonably available information, in a fit-for-purpose approach, to develop a risk evaluation that relies on the best available science and is based on the weight of the scientific evidence. EPA will apply its systematic review process to ensure the quality of its risk evaluation of 1,3-butadiene. The Agency will consider all plausible pathways of exposure for relevancy to the risk evaluation. Considering all monitoring levels measured in the environment provides the EPA with a more thorough understanding of 1,3-butadiene distribution, instead of only considering significant monitoring levels.

A preliminary review of the data show that wastewater treatment of 1,3-butadiene yields a 97% total removal (0.02% by biodegradation, 0.53% by sludge, 96% by volatilization to air; estimated) of this chemical ([U.S. EPA, 2012](#)). Thus, EPA expects some release of 1,3-butadiene to the environment, including surface water where aquatic organisms may be exposed to this chemical. Correspondingly, and pending a thorough review of the systematic review data, general population consumption of fish may yield an oral exposure to 1,3-butadiene. According to the Agency for Toxic Substances and Disease Registry (ATSDR), 1,3-butadiene has been measured at very low levels in rubber or plastic of food packaging and has been found occasionally in food samples. Overall, exposure to 1,3-butadiene through consumption of food and drinking water is expected to be very low in comparison to exposure through inhalation of contaminated air ([ATSDR, 2012](#)). Also, with regard to drinking water, although the general population is exposed to low levels of 1,3-butadiene in U.S. drinking water supplies, the general population exposure via the drinking water pathway is not in scope for this chemical because it is covered under the Safe Drinking Water Act ([NTP, 2016](#), [ATSDR, 2012](#)).

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0030) provided a list of comments related to the Draft Scope Document for 1,3-butadiene:

1. In Section 2.3.3, data are presented as totals to various environmental media, but EPA does not discuss the methodology or how the data will be used;
2. Styrene is not a suitable surrogate for 1,3-butadiene.
3. Production volume does not correspond to occupational exposure;
4. The dermal route should not be considered;

5. It is unnecessary to evaluate dermal exposure for the use of 1,3-butadiene for commercial use of synthetic rubber;
6. Due to the characteristics of 1,3-butadiene, inhalation is most likely route of exposure. However, the conceptual model for industrial and commercial activities and uses and Appendix F, the Life Cycle Analysis for “Processing of 1,3-butadiene as a reagent or monomer (Polymerization)” include a dermal pathway for workers during unloading and sampling and it is recommended that the dermal route should not be included for these activities; and
7. The evaluation of dermal exposure through contact with the material in liquid form may not be necessary for the commercial stage of commercial products that use synthetic rubber as a raw material in their manufacturing process.

Response: In regard to item 1, EPA provides a summary of the information reported to TRI as totals, but site-specific information is reported through the TRI program. EPA considers the information reported through the Toxics Release Inventory (TRI) program to be one reasonably available source of information for the environmental release assessment, but EPA will consider all of the reasonably available information gathered during systematic review. More detailed information on the data analysis and integration will be provided in the draft risk evaluation; at that time, EPA will have considered all reasonably available information to present a draft environmental release assessment in the draft risk evaluation.

For item 2, EPA appreciates this information and plans to consider potential surrogate information, as needed, during the risk evaluation phase based on thorough review of all reasonably available information. For the final scope document, EPA does not include an example surrogate.

For item 3, EPA has found that production volume is one of many factors to consider when mapping conditions of use to occupational exposure and release scenarios.

For item 4, EPA has revised the scope document to indicate that routine dermal exposure of compressed 1,3-butadiene is not expected due to concerns of frostbite. Butadiene is transported as a liquid under pressure, and contact with rapidly vaporizing liquid can cause frostbite, so EPA does not expect routine dermal exposure under these conditions. EPA will review reasonably available information on the conditions of use where the chemical is handled in such a manner. Dermal exposure for the commercial use of plastic and rubber products, not otherwise stated is not expected.

For items 5, 6, and 7, EPA will take this information into consideration when developing exposure scenarios, including the relevant routes of exposure, for 1,3-butadiene.

*Comment: A comment (EPA-HQ-OPPT-2018-0446-0034) stated “The Draft Scope appears to contain a significant reliance on generic and template language” and urged EPA to include information specific to *p*-dichlorobenzene (*p*-DCB) in its final scope. The commenter also offered two questions on the details of the final scope document:*

1. Plastic material and resin manufacturing is referenced in Table 2-2. Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation. Are there specific plastics or resin products that the EPA will be evaluating?
2. What specific endpoints for environmental and human health hazards will the EPA evaluate?

Response: In regard to item 1, EPA is evaluating various uses of p-dichlorobenzene in the plastics manufacturing process (as a reactant or intermediate) and its use in formulations and articles. EPA is considering various plastic or resin types including, but not limited to, an engineering plastic polyphenylene sulfide (PPS), typically a high-performance thermoplastic.

In regard to item 2, EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined ([U.S. EPA, 2018](#)). This data evaluation phase is where the studies' key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding sentinel exposures, and risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038), in regard to Section 2.7.3 of the Draft Scope Document for 1,3-butadiene, recommended: (1) adding mode of action (MOA) for non-cancer; (2) dropping route-to-route as inhalation is the only pathway; (3) dropping allometric scaling; and (4) dropping benchmark dose modeling for oral route.

Response: Section 2.7.3 is specific to environmental hazards. While the primary route of exposure to 1,3-butadiene is inhalation, the general population may be exposed via the oral route (i.e., fish ingestion) and organisms may be exposed by multiple pathways. If applicable, scaling will be applied. At this stage, it is premature to drop route-to-route extrapolation methods. As EPA acquires additional information through its systematic review of 1,3-butadiene, these suggestions will be considered where applicable.

Comment: A commenter (EPA-HQ-OPPT-2018-0462-0038) asserted that EPA's analysis plan for 4,4'-(1-methylethylidene)bis[2, 6-dibromophenol] (TBBPA) should build on the Agency's Work Plan Chemical Problem Formulation and Initial Assessment, as well as its work on Flame Retardants in Printed Circuit Boards. The commenter stated "There are many studies that EPA cites in the Work Plan document in particular that are not specifically referenced in the draft scope document. Consideration of the work the Agency has already done on TBBPA should help as it moves forward with the risk evaluation process. Clearly, there is a need to supplement the previous work by the Agency on TBBPA given the gap in time between the Work Plan document and the risk evaluation process. EPA should seek additional information from the manufacturers and downstream users of TBBPA and incorporate [the commenter]'s past research on TBBPA into the scope document. EPA also states for environmental and occupational exposures that it plans to review 'data for surrogate chemicals that have uses and chemical and physical properties similar to TBBPA.' The Agency should provide more details on how it will approach the use of any surrogate chemical data and address potential areas of uncertainty. In addition, as part of its environmental hazard assessment of TBBPA, EPA currently plans to consider a persistent, bioaccumulative, and toxic (PBT) assessment. Such an approach is not part of procedures for chemical risk evaluation under TSCA, and consideration of a PBT assessment should be removed from the final scope document."

Response: As specified by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA is gathering reasonably available information to conduct the risk evaluation. EPA will also consider all

information provided in public comments during the risk evaluation process for TBBPA. Following the review of the reasonably available information, EPA will determine if there are data gaps or areas of uncertainty and the extent to which information on analogous chemicals will be utilized, as appropriate. EPA is also working with the commenter to obtain proprietary studies so they can be systematically reviewed.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0038) noted, in regard to the conceptual model in the scope document, that “EPA addresses other statutory authorities managed within the Agency that impact the scope of the risk evaluations, such as the Clean Water Act (CWA), the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), and the Resource Conservation and Recovery Act (RCRA). In cases where these are relevant, EPA has added this information to the scope document. This includes, in some cases, a graphical overlay of the relevant authority onto the conceptual model, such as Figure 2-10 in the draft scope for 1,3-butadiene. These visual representations are a welcome addition to the scope document and help clarify EPA’s scoping decisions. However, Figure 2-11 in the 1,3-butadiene scope is difficult to understand, and the color gradients chosen are confusing. The reader will find more helpful and clear information in Appendix H regarding the explanation for what is in and out of scope. These should be improved in the final scopes and future iterations of scope documents by the Agency. Including general population exposures in the scopes for the next 20 risk evaluations is prominent and represents a different approach than the first 10 risk evaluations.”

Response: EPA appreciates this feedback regarding the risk evaluation process. No changes have been made regarding the shading of the diagrams. The shading in the second figure (2-16) indicates inter-media pathways that are out of scope. For example, since 1-3 butadiene is a hazardous air pollutant (HAP), Water, Sediment and Soil are partially shaded red as pathways from air to these media (e.g., condensation and fugitive emissions) are out of scope.

Potentially Exposed or Susceptible Subpopulations

Comment: One commenter (EPA-HQ-OPPT-2018-0426-0020, EPA-HQ-OPPT-2018-0427-0035, EPA-HQ-OPPT-2018-0428-0025, EPA-HQ-OPPT-2018-0444-0029, EPA-HQ-OPPT-2018-0451-0031, EPA-HQ-OPPT-2018-0488-0031) asserted that EPA must identify people living in geographic areas near high-volume chemical facilities in Texas and Louisiana as potentially exposed or susceptible subpopulations. The commenter notes that “[n]one of the draft scopes identify as [PESS] people living in geographic proximity to high-volume chemical facilities in Texas and Louisiana, including facilities that release and/or transfer high volumes of multiple TSCA high-priority chemicals as well as other toxic industrial chemicals of concern[, but] . . . several of the scope documents acknowledge that people living near manufacturing, processing and disposal sites do in fact have potentially higher exposures to the TSCA high priority chemicals.” In addition, the commenter identified where “fence line communities have higher exposures than the general population” in the draft scope documents *o*-dichlorobenzene (*o*-DCB), 1,3-butadiene, 1,1-dichloroethane (1-1-DCA), 1,2-dichloroethane, 1,2-dichloropropane (1,2-DCP), and ethylene dibromide (EDB).

Response: During the Prioritization process, EPA identified the following potentially exposed or susceptible subpopulations based on Chemical Data Reporting (CDR) information and studies reporting developmental and reproductive effects: children, women of reproductive age (including, but not limited to pregnant women), workers and consumers. EPA plans to evaluate potentially exposed or susceptible subpopulations, as appropriate, in the risk evaluation. As noted in the scope document, certain exposure pathways are not within the scope of the risk evaluation. Specifically, identified exposure pathways, including exposure to the general population and certain potentially exposed susceptible

subpopulations, covered under the jurisdiction of other EPA-administered statutes and regulatory programs are not within the scope of the risk evaluation. Language about what pathways are under the jurisdiction of other EPA-administered statutes will also be included in the draft Risk Evaluation.

Human health and environmental hazards, as well as environmental and human exposures, were considered during the development of the TSCA scope documents for all High-Priority Substances. This information informed the Agency's identification of potentially exposed or susceptible subpopulations listed in the final scope documents. In developing exposure scenarios later in the risk evaluation process, EPA plans to analyze reasonably available data to ascertain whether some human receptor groups may be exposed via exposure pathways that may be distinct to a particular subpopulation or life stage (e.g., children's crawling, mouthing or hand-to-mouth behaviors) and whether some human receptor groups may have higher exposure via identified pathways of exposure due to unique characteristics (e.g., activities, duration or location of exposure) when compared with the general population. Likewise, EPA plans to evaluate reasonably available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).

Communities living in close proximity to identified sources of emissions from manufacturing, processing, use or disposal may experience greater exposure than the general population. In reviewing the reasonably available exposure information, EPA considers the spatial and temporal relevance of the information in building each exposure scenario for the identified conditions of use, including any information regarding chemical emissions. EPA has not completed its full evaluation, synthesis and integration of the exposure literature. EPA acknowledges that exposures (and any subsequent risk) vary due to differences among individuals, populations, spatial and temporal scales and other factors and strives to present both a central tendency and a high-end estimate. In estimating exposures, EPA utilizes guidance as provided in EPA's Guidelines for Human Exposure Assessment ([U.S. EPA, 2019](#)) which defines "High-End" as the 90% to 99.99% exposure.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0022, EPA-HQ-OPPT-2018-0426-0020, EPA-HQ-OPPT-2018-0427-0035, EPA-HQ-OPPT-2018-0428-0025, EPA-HQ-OPPT-2018-0451-0031, EPA-HQ-OPPT-2018-0462-0032, EPA-HQ-OPPT-2018-0465-0032) stated "For three of the TSCA high-priority chemicals, the TX/LA Gulf region experiences more than one-half the releases of the chemical in the entire United States: TBBPA (76.9 percent of all U.S. releases); 1,3-butadiene (73.6 percent of all U.S. releases); and 1,1-DCA (54.8 percent of all U.S. releases). In addition, for five of the TSCA high-priority chemicals, this region experiences more than 70 percent of the incoming waste transfers of the chemical in the United States: 1,1-DCA (95.1 percent of all U.S. incoming waste transfers); [1,1,2-Trichloroethane ([1,1,2-TCE])] (86.6 percent of all U.S. incoming waste transfers); trans-1,2-dichloroethylene (80.6 percent of all U.S. incoming waste transfers); 1,2-DCP (89.3 percent of all U.S. incoming waste transfers); 1,3-butadiene (75.4 percent of all U.S. incoming waste transfers); and EDC (72.2 percent of all U.S. incoming waste transfers). These data underscore that people in this region have far greater exposure to these chemicals, as well as many of the other high-priority chemicals, than does the general population—a fact that EPA must take into account in its risk evaluations."

Comment: The same commenter (EPA-HQ-OPPT-2018-0421-0022) asserted that "To fully characterize the risks to people living in geographic proximity to high-volume chemical facilities in Texas and Louisiana, EPA must gather and develop information about exposures directly from these communities." The commenter states that "EPA must actively seek input from exposed communities on the high-priority chemicals because this information is 'reasonably available' and directly relevant to

understanding the conditions of use of the TSCA high-priority chemicals, as well as information about exposure to these substances.” The commenter pointed out that Office of Pollution Prevention and Toxics is identified as the Agency’s Environmental Justice 2020 program lead in meeting the objective of “ensur[ing] environmental justice is appropriately analyzed, considered and addressed in EPA rules with potential environmental justice concerns, to the extent practicable and supported by relevant information and law.” The commenter noted that while TSCA risk evaluations are not rulemakings, any finding of unreasonable risk must be followed by a risk management rulemaking and such risk management can only protect fence line communities if the underlying risk evaluation takes environmental justice concerns into account.

Comment: Another commenter (EPA-HQ-OPPT-2018-0438-0042) also noted that populations living in certain areas of Arkansas, Tennessee, Texas, and Louisiana should be considered highly exposed and susceptible populations. In addition, the commenter stated that workers who may be exposed at formaldehyde facilities and live in nearby communities are even more exposed. The commenter reviewed data on Clean Air Act compliance, formaldehyde emitting facilities and mobile home parks in those areas.

Response: In the next 20 High-Priority Substances risk evaluations, EPA plans to assess exposures to various populations, including occupational, consumer and the general population, as appropriate. The general population exposure will specifically include fence line populations, that is, those that are most likely to be exposed due to proximity to facilities emitting or discharging the High-Priority Substance. Exposures to subsets of this general population, such as children and pregnant women, will also be considered as appropriate in EPA’s fit-for-purpose risk evaluations.

EPA will continue to refine its processes for risk evaluations to identify and determine risks to potentially exposed or susceptible subpopulations as required by TSCA. “Potentially exposed or susceptible subpopulations” may include subpopulations with unique exposure circumstances relative to the general population, such as tribes, and will be considered as part of the risk evaluation process for each of the High-Priority Substances. EPA also remains committed to ensure environmental justice is integrated into EPA’s programs to strengthen environmental and public health protections. TSCA requires EPA to consider potentially exposed or susceptible subpopulations as part of the risk evaluation process, which the Agency views as carrying out the spirit of Executive Order 12898.

In determining the exposure estimates associated with the identified conditions of use, EPA incorporates variability and uncertainty into its estimates, presenting a central tendency and high-end estimate and includes a range of intake values for expected routes of exposure, to account for differences across populations. However, EPA acknowledges that populations living in close proximity to identified sources of emissions from manufacturing, processing, use or disposal may experience greater exposure than the general population. In reviewing the reasonably available exposure information, EPA considers the spatial and temporal relevance of the information in building each exposure scenario for the identified conditions of use. EPA also acknowledges and understands that tribes and other susceptible subpopulations have unique exposure circumstances relative to the general population that may lead to exposure pathways not experienced by the general population. In reviewing the reasonably available literature and the pathways of exposure from the conditions of use of each chemical, EPA plans to evaluate whether and how those pathways may intersect with tribal exposure circumstances and other susceptible populations.

As explained in more detail in Section 2.6 of the scope documents, 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 each of the 20 High-Priority Substances using authorities in TSCA sections 6(b) and 9(b)(1).

For many of the chemicals raised in the comment, EPA has found that general population exposures from releases to environmental media, including air, water, and land, are under the jurisdiction of other EPA-administered statutes and associated regulatory programs. As a result, EPA does not plan to evaluate general population exposures from these pathways in the risk evaluations for those chemicals.

To the extent that specific exposure pathways are not under the jurisdiction of other EPA-administered statutes and associated regulatory programs, EPA plans to evaluate those exposures in the risk evaluations for the individual substances.

Comment: One commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) stated that a significant part of exposure can be attributed to the ambient air and indoor air pathways and that EPA cannot properly identify the potentially exposed or susceptible subpopulations if it ignores pathways which cause subpopulations to be identified as such.

Response: EPA includes consideration and identification of several potentially exposed or susceptible subpopulations within the draft scope document (see Section 2.5). For each chemical substance, this may include women of reproductive age within the workplace as well as women of reproductive age who are consumer users and bystanders. Potentially exposed or susceptible subpopulations may also include infants, children, and the elderly, among others.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036) asserted that EPA has failed to identify all relevant PESS. The commenter pointed to three paragraphs in the draft scopes, asserting that EPA "merely quote[s] TSCA's definition of the term and repeat[s] EPA's earlier identification at the prioritization stage of the broad categories of "children, women of reproductive age (e.g., pregnant women), consumers and workers" as comprising such subpopulations." The commenter also noted that EPA must include infants, children, pregnant women, workers, and the elderly among such subpopulations, per TSCA, citing 15 U.S.C. § 2602(12). The commenter stated "In the scopes, EPA also has not, but must, identify other subpopulations that EPA has reason to expect could be subject to greater susceptibility. For 1,3-butadiene, for instance, in the earlier dossier EPA noted that '[s]mokers, those exposed to secondhand smoke, and individuals inhaling smoke from wood fires would also be exposed to higher levels of 1,3-butadiene.' Yet in the draft scope for this chemical, EPA omitted this statement and did not identify these subpopulations as 'potentially exposed or susceptible.' Instead it merely states that 'EPA plans to evaluate available human health hazard information to ascertain whether some human receptor groups may have greater susceptibility than the general population to the chemical's hazard(s).' The scope document must identify such subpopulations with greater potential susceptibility as potentially exposed or susceptible subpopulations."

Response: EPA disagrees that the potentially exposed or susceptible subpopulations identified for each chemical substance must be limited to infants, children, pregnant women, workers, and the elderly. TSCA section 3(12) lists examples of human receptors that may be considered PESS but provides for EPA to identify the relevant subpopulations for each chemical substance.

EPA acknowledges that receptors living in close proximity to identified sources of emissions from manufacturing, processing, use or disposal may experience greater exposure than the general population. In reviewing the reasonably available exposure information, EPA considers the spatial and temporal relevance of the exposure information in building each exposure scenario for the identified conditions of use, including any information regarding chemical emissions. EPA has not completed its full evaluation, synthesis and integration of the exposure literature.

In the 1,3-butadiene draft scope document, EPA summarized two studies that identified concentrations of 1,3-butadiene in air; however, EPA also indicated that emission pathways to ambient air from commercial and industrial stationary sources and associated inhalation exposure of the general population or terrestrial species are covered under the jurisdiction of the CAA.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042), in regard to formaldehyde, stated that fence line communities have a higher exposure than the general population but EPA inexplicably treated these duration and location specific exposures as a general population exposure.

Response: EPA excluded formaldehyde releases associated with ambient air from stationary sources from the scope of the risk evaluation because such releases are covered under the jurisdiction of other EPA administered statutes (specifically the CAA and RCRA). This includes both general population exposures and potentially exposed or susceptible subpopulations within the general population which are impacted by such stationary source emissions.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0025, EPA-HQ-OPPT-2018-0433-0037) asserted that tribes clearly meet the definition of PESS but are not included in the PESS that EPA has listed in the scoping documents, making that list incomplete, and leaving tribal risks out of any future risk assessment. The commenter stated that “Not only would the continued exclusion of tribes from risk assessment be in violation of TSCA, it would also be in violation of EPA’s commitment to integrating environmental justice into the development, implementation, and enforcement of environmental laws, regulations, and policies.” The commenter also cited Executive Order 12898 on Environmental Justice and asserted “Tribes are a minority and low-income population whose lifeways place them at higher exposure potential to chemicals in the natural environment so that EPA must include exposure scenarios representative of tribal lifeways in its TSCA risk assessment process. In not doing so, tribal risks are left unevaluated, and tribes are left with a disproportionate share of the negative consequences and effects resulting from EPA’s TSCA policies and operations.” The commenter elaborated “tribes have unique lifeways that place them at different risk due to multiple exposure pathways not experienced by the general population.” According to the commenter, lifeways include higher fish and wild game consumption; housing that often tends to be substandard; less stringent worker safety practices and enforcement; and lower quality of drinking water sources due to lack of regulation or infrastructure. The commenter noted the Agency’s Science Advisory Committee on Chemicals (SACC) report on cyclic aliphatic bromide cluster (and 1,4-dioxane from November 2019), which also urged EPA to give special consideration of tribes for many of these same reasons. The commenter also provided multiple aggregate exposures as justification for including tribes as PESS, including closer proximity to conditions of use such as disposal.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026) asserted that EPA should follow recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability. The commenter noted that “across a population, typically the highest chemical exposures are to workers and communities near industrial facilities/contaminated sites. Such communities are often low income and/or people of color, exposed to a disproportionate share of pollution, environmental hazards, social and economic stressors.” The commenter stated that exposure disparities (such as from proximity to polluting industries or use of consumer products), social vulnerabilities (such as lack of access to health care) and biological susceptibilities (such as age or pre-existing disease) create differences in how chemicals affect a person’s health, contributing to adverse health outcomes and disparities for vulnerable populations throughout the lifespan. To protect susceptible groups as required by law, EPA’s risk evaluations must be aligned with evidence-based principles to protect public health.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0034, EPA-HQ-OPPT-2018-0434-0037, EPA-HQ-OPPT-2018-0501-0041, EPA-HQ-OPPT-2018-0503-0032, EPA-HQ-OPPT-2018-0504-0041) asserted that the draft scope documents for phthalates fail to identify relevant information on hazards and potentially exposed or susceptible subpopulations that is required to conduct a cumulative risk evaluation. The commenter stated that omission of these critical factors not only violates TSCA’s requirements, but also prevents the disclosure of information that is critical to conducting a cumulative risk evaluation on the phthalates designated as High-Priority Substances.

Comment: Another commenter (EPA-HQ-OPPT-2019-0131-0047) stated that formaldehyde draft scope failed to specify many human health hazards acknowledged in a recent EPA rulemaking.

Response: TSCA does not require the EPA to assess a common mode of action or common adverse outcomes (i.e., a cumulative risk evaluation). EPA acknowledged several human health hazards in the Formaldehyde Emission Standards for Composite Wood Products final rule preamble (see 40 CFR 770); however, it should be noted that the rulemaking was explicitly authorized and driven by Congress and the Formaldehyde Standards for Composite Wood Products Act of 2010 (see 15 U.S.C. § 2697), which set formaldehyde emissions for three composite wood products and authorized the Agency to regulate laminated products.

As described in the scope documents, EPA has initiated the process of searching for, collecting, and screening the data and information for the scopes of the next 20 High-Priority Substances, and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Consistent with the process outlined in EPA’s [Application of Systematic Review in TSCA Risk Evaluations](#), following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding sentinel exposures, and risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations.

The most prominent aspect of cumulative risk assessment is often the prediction of the combined effects of multiple stressors. In circumstances where EPA determines it is appropriate to conduct a cumulative risk assessment for a particular chemical substance, in its synthesis and evidence integration phase, EPA will integrate the hazard and dose-response relevant to the stressor(s) of interest and perform an analysis of exposure(s) to those stressor(s) including reviewing information related to the integration of exposure, hazard, and dose-response information that could be applicable to a cumulative risk assessment. These include multiple-stressor hazard, dose-response and exposure issues, exposure time or duration-related issues, susceptibility of the study population along with the influencing factors (including life stage), and subpopulations with special exposures.

Comment: A commenter (EPA-HQ-OPPT-2018-0433-0034, EPA-HQ-OPPT-2018-0434-0037, EPA-HQ-OPPT-2018-0501-0041, EPA-HQ-OPPT-2018-0503-0032, EPA-HQ-OPPT-2018-0504-0041) noted “In each of the Draft Phthalate Scopes, EPA identifies ‘infants, children, pregnant women, workers, and the elderly’ as a potentially exposed or susceptible subpopulation, as TSCA requires.” The commenter asserted “However, given the strong evidence that the developing fetus is exposed to multiple phthalates, and the fact that prenatal phthalate exposure can lead to catastrophic health outcomes, the developing fetus should be explicitly considered a potentially exposed or susceptible subpopulation. A failure to evaluate the developing fetus as such will lead to a vast underestimation of risk to the most susceptible life stage to phthalate exposure.”

Response: EPA disagrees that the potentially exposed or susceptible subpopulations identified for each chemical substance must include infants, children, pregnant women, workers, and the elderly. TSCA section 3(12) lists examples of human receptors that may be considered PESS, but provides for EPA to identify the relevant subpopulations for each chemical substance. However, EPA recognizes and agrees that the fetus may be exposed to chemical stressors and that the fetus is potentially exposed via maternal exposures. EPA is aware of critical windows of exposure for some adverse effects on the reproductive system associated with gestational exposures in humans and animals. As such, women of reproductive age are considered PESS for the phthalates designated as High-Priority Substances.

EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding sentinel exposures, and risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure-related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops, including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) stated “Subpopulations with greater exposures than the general population are PESSs under TSCA and the law requires EPA to determine whether their higher exposures present an unreasonable risk of injury. However, in most of the first 10 risk evaluations, EPA failed to combine dermal and inhalation exposure to derive composite risk estimates even though it recognized that these two routes of exposure often occur simultaneously for workers and consumers. EPA also failed to account for the risks to subpopulations exposed to a chemical by multiple pathways (consumer, occupational and environmental). People who are exposed to chemicals on the job and at home and from the ambient environment are PESSs under TSCA. The 20

upcoming risk evaluations must identify such subpopulations, estimate overall exposure for each and determine whether the total risk to the subpopulation is unreasonable.”

Response: The magnitude, frequency, and duration of exposures and the associated routes of exposure will depend upon the conditions of use. EPA acknowledges that workers, consumers and the general population may be exposed via the inhalation, dermal and oral routes and that these exposures may be additive across routes, pathways, receptors and chemical stressors. Exposure scenarios will be developed based on the reasonably available information, weight of the scientific evidence and best available science approaches. Aggregate assessments may not be appropriate in all cases; for example, if there is not sufficient information that can be reliably modeled to perform additive inhalation and dermal exposures. In addition, for some assessments, an aggregate exposure approach may rely on the availability of a pharmacokinetic model (as in the draft risk evaluation of N-Methylpyrrolidone (NMP)). For other assessments, there may be information of sufficient quality and relevance to consider another approach such as the use of both monitored and modeled exposure values in conjunction with human health hazard information (such as was utilized for the draft risk evaluation of Cyclic Aliphatic Bromide Cluster (HBCD)). EPA has not yet completed its evaluation, syntheses and integration of the available literature and is not yet able to discern the best fit approach for each High-Priority Substance evaluation.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0048) asserted that the TSCA definition of PESS also includes subpopulations at greater risk because of their greater susceptibility to the health effects of chemicals. The commenter stated “For the initial 10 chemicals, EPA’s evaluations identify several conditions that increase susceptibility, such as life-stage, sex, genetic polymorphisms, race/ethnicity, preexisting health status, lifestyle factors, and/or nutrition status. However, identifying these PESSs is only the first step under TSCA. EPA must also determine whether the chemical presents an unreasonable risk to the PESS – a step that EPA has not taken for the initial 10 chemicals.” The same commenter urged EPA in the upcoming evaluations to assess the degree of increased risk to each susceptible subpopulation and then determine whether this increased risk is unreasonable. The commenter also suggested the use of uncertainty factors where there are uncertainties in such analyses, consistent with other susceptible groups, such as infants and children.

Response: As described in the scope documents, EPA has begun the process of searching for, collecting, and screening the data and information for the scopes of the next 20 High-Priority Substances, and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure-related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations. The ability to assess the degree of increased risk due to specific susceptibilities will depend on the quality and relevance of the reasonably available information. When there is evidence of susceptibilities, but specific studies addressing these susceptibilities are unavailable for quantitative analysis, susceptibility data may support the use of uncertainty factors (UFs), refined human variability

UFs for non-cancer risk benchmarks or uncertainty analyses and potential susceptibilities for noncancer and cancer.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) asserted that EPA must consider and account for social conditions that can enhance the susceptibility of some populations to negative health outcomes associated with environmental exposures to the chemical being evaluated. The same commenter noted that scholarly research has demonstrated that communities of color, low-income communities, and Indigenous communities face greater environmental and health hazards compared to communities with more white or affluent people and evidence has revealed that these communities face extreme threats to their health from their environments that can further compound the negative effects of environmental exposures on these populations.

Response: EPA includes consideration of and identification of several potentially exposed or susceptible subpopulations within the draft scope document (see Section 2.5). For each chemical substance, this may include women of reproductive age within the workplace as well as women of reproductive age who are consumer users and bystanders. Potentially exposed or susceptible subpopulations may also include infants, children, and the elderly, among others. TSCA requires EPA to consider PESS as part of the risk evaluation process, which the Agency views as carrying out the spirit of Executive Order 12898 relating to environmental justice in minority populations and low-income populations.

Additionally, many of the factors identified are included within the approach EPA takes in its risk evaluations. EPA may include individuals who may have existing health conditions as potentially exposed or susceptible subpopulations within the draft scope document. When the impact of ambient air is considered in the scope documents, concentrations are obtained (or modeled) at the fence line which is approximately 100 meters away from the emitting source(s). This distance may align with nearby residences in minority population and low-income areas. Affected populations may have increased exposure due to the building of pre-fabricated houses/trailers which may utilize materials which off-gas formaldehyde. As identified in the draft scope document, EPA intends to consider off-gassing of formaldehyde from building materials not otherwise addressed. Such consideration includes consumer exposure, including consumer and bystander exposure resulting from activities utilizing building products.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) mentioned that it has been well-documented that stark relationships that exist between social position and negative health outcomes. Health disparities for racially and/or economically marginalized groups have been hypothesized to occur via social and biological responses to: (1) economic and social deprivation; (2) exposure to toxic substances and hazardous conditions; (3) socially inflicted trauma (including generational trauma); (4) targeted marketing of unhealthy commodities; and (5) inadequate access to health care centers and providers.

Response: EPA will consider these suggested health disparities as it finalizes the analysis plan for consumer and environmental exposures. EPA will also utilize data identified during its systematic review process and submitted as part of responses to comments related to these recommendations, if available, to inform the development of exposure scenarios falling under the conditions of use to be evaluated in this risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) asserted that EPA acknowledges the statutory requirement to identify potentially exposed or susceptible

populations, but then fails to do so and lists the exemplary vulnerable subpopulations in the statutory definition and provides no meaningful specificity to the identity of the subpopulations, or the methodology to be employed to comply with the statutory requirement. The commenter identified the counties with the most exposed subpopulations in the country to ambient air emissions of: (1) formaldehyde alone; and (2) formaldehyde and other chemicals contributing to risks associated with formaldehyde exposure. The commenter identified locations nationally where mobile home parks are close to formaldehyde emitters. Using TRI emissions data, the commenter identified 1,572 facilities across 858 counties with formaldehyde emissions between 2000 and 2018 and used the TRI database to locate emissions of chemicals classified as respiratory carcinogens in the EPA IRIS database. The commenter found 647 counties across the country that had facility-level emissions of formaldehyde, and at least one of the IRIS respiratory carcinogens (19 counties that had facility-level emissions of formaldehyde and nine or more of the IRIS respiratory carcinogens).

Response: EPA includes consideration of and identification of several PESS within the draft scope document (see Section 2.5). PESS may include infants, children, and the elderly, among others. As described in the scope documents, EPA has initiated the process of searching for, collecting, and screening the data and information for the scopes of the next 20 High-Priority Substances, and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies' key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding sentinel exposures, and risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations.

EPA excluded formaldehyde releases associated with ambient air from stationary sources from the scope of the risk evaluation because such releases are covered under the jurisdiction of other EPA administered statutes (specifically the CAA and RCRA). This includes both general population exposures and potentially exposed or susceptible subpopulations impacted by such stationary source emissions.

However, neither the CAA nor RCRA cover air emissions resulting from consumer activities associated with the installation of products containing formaldehyde that may off-gas formaldehyde following installation. This off-gassing could impact individuals living nearby or adjacent to the residence where the consumer installation activity occurred. Therefore, EPA includes consideration of formaldehyde exposure to co-located or co-residence individuals (and associated potentially exposed or susceptible subpopulations that are co-located or co-residence) due to consumer activities associated with off-gassing from building materials not otherwise addressed within the scope of this risk evaluation.

The risk evaluation is specific to formaldehyde, not co-exposure to other (non-formaldehyde) chemicals. However, EPA will consider the information provided as it develops approaches and methodology to identify relevant health hazards. EPA will also utilize data identified during its systematic review process and submitted as part of responses to comments related to these recommendations, if available,

to inform the development of exposure scenarios falling under the conditions of use to be evaluated in this risk evaluation as well as health and environmental endpoints.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA has failed to identify all relevant PESS, failing to meet the requirements of TSCA § 6(b)(4)(D), which requires that EPA consider “potentially exposed or susceptible subpopulations” when evaluating chemicals. The commenter stated “In each draft scope, EPA provides three boilerplate paragraphs on ‘potentially exposed or susceptible subpopulations’ (section 2.5, see pp. 35-36 of the formaldehyde draft scope for an example). These paragraphs merely quote TSCA’s definition of the term and repeat EPA’s earlier identification at the prioritization stage of the broad categories of ‘children, women of reproductive age (e.g., pregnant women), consumers and workers’ as comprising such subpopulations.” According to the commenter “EPA makes clear it has yet to develop and present the required reasonably available information necessary to identify specific subpopulations that may be more highly or differentially exposed, or more susceptible to exposures.” Pointing to several passages of “boiler plate language” throughout the scope, the commenter asserts that “EPA merely repeats these sentences” and “does not actually identify people exposed to or in proximity to such sources as ‘potentially exposed or susceptible subpopulations.’” The commenter also asserted that EPA has not identified other subpopulations that EPA has reason to expect could be subject to greater susceptibility, citing an example from the 1,3-butadiene draft scope in which EPA did not identify smokers, those exposed to secondhand smoke, and individuals inhaling smoke from wood fires as PESS.

Response: During the prioritization process, EPA PESS based on CDR information and studies reporting developmental and reproductive effects. In addition, PESS could include subpopulations with unique exposure circumstances and individuals who may have existing health conditions, which will be considered as part of the risk evaluation process for each of the High-Priority Substances. As described in the scope documents, EPA has initiated the process of searching for, collecting, and screening the data and information for the scopes of the next 20 High-Priority Substances, and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding sentinel exposures, and risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations.

EPA plans to consider biological susceptibility in its evaluation of exposure and human health hazard. EPA has not yet completed the data evaluation and evidence integration steps of the systematic review process and is reviewing the reasonably available human health hazard information to identify the appropriate hazards and susceptibilities associated with each High-Priority Substance.

Comment: One commenter (EPA-HQ-OPPT-2018-0426-0024, EPA-HQ-OPPT-2018-0427-0039, EPA-HQ-OPPT-2018-0428-0030, EPA-HQ-OPPT-2018-0444-0032, EPA-HQ-OPPT-2018-0451-0035, EPA-HQ-OPPT-2018-0488-0037) urged EPA to follow NAS recommendations to identify susceptible subpopulations based on established extrinsic and intrinsic factors that increase vulnerability. The

commenter stated “typically the highest chemical exposures are to workers and communities near industrial facilities/contaminated sites. Such communities are often low income and/ or people of color, exposed to a disproportionate share of pollution, environmental hazards, social and economic stressors.” The commenter identified in six draft scope documents (1,3-butadiene, 1,1-dichloroethane, 1,2-dichloroethane, 1,2-dichloropropane, ethylene dibromide, and *o*-dichlorobenzene) where EPA outlines that there are portions of the general population which may have higher exposure. The commenter asserted that “EPA is acknowledging these populations have a higher likelihood of exposure due to their geography but failing to categorize most of them as eligible for consideration as a potentially exposed or susceptible subpopulation.”

Response: Human health and environmental hazards, as well as environmental and human exposures, were considered during the development of the scope documents based upon what was known about each of the High-Priority Substances. This information informed the Agency’s identification of potentially exposed or susceptible subpopulations listed in the final scope documents. “Potentially exposed or susceptible subpopulations” could include subpopulations with unique exposure circumstances, such as tribes, and will be considered as part of the risk evaluation process for each of the High-Priority Substances.

In determining the exposure estimates associated with the identified COU, EPA incorporates variability and uncertainty into its estimates, presenting a central tendency and high-end estimate and includes a range of intake values for expected routes of exposure, to account for differences across populations.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) commented on EPA’s inclusion of workers as PESS and stated “not all workers are equally susceptible, and simply identifying workers as a potentially exposed and susceptible subpopulation does not satisfy EPA’s obligation to explain how it plans to ‘assess exposures, effects, and risk’ to the most susceptible workers.” The commenter asserted “In the first ten risk evaluations, EPA often listed factors that could increase susceptibility to the chemical at issue – such as alcohol use, preexisting disease, or genetic polymorphisms – but failed to separately calculate risks to those subpopulations, asserting that ‘to account for variation in sensitivity within human populations[,] intraspecies [uncertainty factors] were applied for noncancer effects.’ EPA did not attempt to evaluate whether those default uncertainty factors were sufficient to account for the specific subpopulations’ increased susceptibility, and offered no increased protection for subpopulations that may be at greater risk of cancer risks. The scopes must go beyond the mere identification of potentially exposed or susceptible subpopulations and also explain EPA’s plans for ensuring that the next twenty risk evaluations fully and accurately evaluate the risks to those populations.”

Response: In identifying PESS, EPA has identified workers as PESS due to their greater exposure. EPA also recognizes that not all workers are equally susceptible. As described in the scope documents, EPA has completed the process of searching, screening and collecting the data and information for the scopes of the next 20 High-Priority Substances and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions including any conclusions regarding sentinel exposures, and risks to potentially exposed or susceptible subpopulations. Because there are many individual factors that may influence susceptibility to exposure related health effects, susceptibilities may differ depending upon the chemical and its conditions of use.

In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations. When there is evidence of susceptibilities, but specific studies addressing these susceptibilities are unavailable for quantitative analysis, susceptibility data may support the use of UFs, refined human variability UFs for non-cancer risk benchmarks or uncertainty analyses and potential susceptibilities for noncancer and cancer.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038), in regard to Section 2.5 of the Draft Scope Document for 1,3-butadiene, recommended that specific information on subpopulations that are potentially sensitive to the effects of 1,3-butadiene due to toxicokinetic factors (e.g., GST-T1 polymorphism) and toxicodynamic factors (e.g., women with low follicle counts, as addressed in Kirman and Grant, 2012; disease states associated with deficiencies in DNA crosslink repair such as Fanconi anemia) be included in the scope here.

Response: Section 2.5 of the revised scope document states “If adverse outcomes are identified for certain ages/sex/organism characteristics, then those populations would be considered PESS.”

Aggregate and Cumulative Exposure

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026) commented on multiple exposure issues, including aggregate exposure across populations; aggregate exposure across pathways; legacy uses; and cumulative assessment. The commenter asserted that EPA must consider aggregate exposure within and across populations; otherwise it will underestimate risk. The commenter also recommended that aggregate exposure should include legacy uses, uses where a chemical is present as a contaminant/by-product, and uses already assessed. The commenter urged EPA to “consider the aggregate exposures within and across these populations [Occupational users and non-users; 2) consumers and bystanders; and 3) general population], or risk will be underestimated due to inaccurate assessment of real-world exposures. Exposures within a population must be aggregated (rather than considered in isolation) in order to sufficiently estimate actual population exposure to the chemical—for example, through exposures from food, water and air.” The commenter also stated “Consumers and workers are part of the general population. As workers and consumers also eat food and drink water, it is reasonable to assume that they will have the same exposures as the general population, in addition to the anticipated exposures on-the-job or from consumer products.” In addition, the commenter stated “Some workers will also be consumer product users, so they have the potential to face general, consumer product, and on-the-job exposures.” The commenter asserted that EPA needs to account for combined dermal and inhalation exposures as these two types of exposure often occur concurrently (e.g., workers) instead of EPA’s proposed approach to account for dermal and inhalation separately. The commenter stated “To accurately account for real-life exposures, EPA needs to aggregate exposures across exposure pathways. EPA has described the concept of assessing aggregate exposures as ‘the risk cup,’ where every use of a chemical contributes to filling the cup . . . However, if known chemical uses and exposures are ignored, the cup levels will be an underestimate of the true risk posed, suggesting that risks are below levels of concern when in reality the cup might be full or overflowing.” The commenter asserted that legacy uses and disposal should also be included as part of the aggregate exposure assessment, considering that many of these 20 chemical substances are contaminants found at Superfund sites across the country.

Comment: Another commenter (EPA-HQ-OPPT-2018-0426-0021) suggested incorporating additional conceptual models that consider aggregate and cumulative exposures in the following ways:

- Consider combined exposures across different routes of exposure (inhalation, oral, dermal) for each population: occupational, consumer, and general.

- Calculate an aggregate exposure of consumer exposures that also account for the exposures that individuals encounter as members of the general population.
- Calculate an aggregate exposure of occupational exposures that also account for exposures that workers or occupational non-users encounter outside the workplace, as consumers and members of the general population.
- General population exposures must include current exposures from past releases to the environment.

Comment: Another commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA’s draft scopes are largely silent on whether EPA intends to assess combined exposures in its risk evaluations of the 20 High-Priority Substances and stated “The presentation of identified conditions of use sheds no light on whether EPA intends to assess the conditions of use individually or collectively. Nor do the Analysis Plans in the draft scopes indicate whether the Agency will pursue a use-by-use analysis or analyze the conditions of use together in a more holistic fashion. In its draft risk evaluations EPA has chosen the former course, failing to follow TSCA’s requirements. In finalizing these scopes, EPA needs to indicate its intent in this regard, and should it continue its recent pattern of not considering combined exposures, provide a full legal rationale for not doing so.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0033) stated “during the anticipated duration of an individual’s work life, there is a significant likelihood that the worker will experience cumulative exposures that exceed the respective health-based values promulgated to protect the general population” and urged EPA “to explicitly consider the cumulative exposures of exposed workers in light of these cumulative exposure guidelines for the general population. Workers should not be subjected to life-time exposures that would be unacceptable for others.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) asserted that the draft scopes fail to consider workers exposed to chemicals through a combination of uses and exposure routes, stating that EPA ignored combined exposures in its last round of risk evaluations, and that the draft scopes indicate EPA’s plans to maintain this unlawfully segmented approach. The commenter stated “While EPA plans to calculate worker risks from inhalation and dermal exposures, and in select instances oral exposures, the draft scopes do not discuss the combined risks to workers who breathe, touch, and/or ingest the same chemical. Nor does EPA account for the fact that many exposed workers are also exposed to the same chemicals outside of work, via consumer products, drinking water, and other pathways. For instance, EPA indicates that workers can be exposed to formaldehyde through inhalation, dermal, and potentially oral exposure routes. EPA also indicates that consumers and bystanders could be exposed to formaldehyde through some of the same routes. Therefore, it is foreseeable that some workers will be exposed to formaldehyde at work, for instance when processing the chemical as a reactant, and then go to a home with particleboard kitchen cabinets and pressed wood flooring, both of which emit formaldehyde. Yet, the draft scopes treat these exposures as if they happen in a vacuum.”

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0038) urged EPA to assess product life cycle and uses as part of an aggregate exposure approach, including legacy use, associated disposal, and legacy disposal. Uses should also consider disproportionate exposures to sensitive populations such as low-income communities that obtain items second-hand and in a state that may be more likely to degrade and increase exposures or contain chemicals that are now phased out for legacy uses. The same commenter also suggested that EPA’s approach to assessing occupational exposure and children’s exposure via hand/mouth activity from second hand or legacy uses should be described in detail.

Comment: A commenter (EPA-HQ-OPPT-2018-0426-0021) encouraged EPA to consider aggregate exposures to “ensure that exposure models and assessments adequately capture, and do not underestimate, exposure.”

Response: 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. This statutory provision does not require EPA to consider aggregate exposures. 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) at 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 at 40 CFR 702.33. EPA plans to consider the reasonably available information and use the best available science to determine whether to consider aggregate or sentinel exposures for a particular chemical.

EPA’s approach for chemical risk evaluations is to assess exposures, hazards and risks for the chemical being evaluated under the conditions of use. EPA welcomes additional information and specific examples that may be applicable to a specific risk evaluation to illustrate the issue for EPA to address.

EPA recognizes that a worker may be exposed via inhalation, dermal and oral routes at the workplace. EPA also recognizes that when the worker leaves the facility, there may be additional exposures from being in the general population and from using consumer products. When conducting the risk evaluations of the first 10 chemicals, EPA generally did not evaluate aggregate exposures due to uncertainties in such an assessment, such as uncertainty in the relative distribution of exposure for each pathway. EPA will evaluate reasonably available data and determine whether to consider aggregate exposure assessment on a chemical-by-chemical basis for the 20 High-Priority Substances.

The magnitude, frequency, and duration of exposures and the associated routes of exposure will depend upon the conditions of use. EPA acknowledges that workers, consumers, and the general population may be exposed via the inhalation, dermal and oral routes and that these exposures may be additive across routes, pathways, receptors and chemical stressors. Exposure scenarios will be developed based on the reasonably available information, weight of the scientific evidence and best available science approaches. For example, for some assessments, an aggregate exposure approach may rely on the availability of a pharmacokinetic model (as in the draft risk evaluation of NMP). For other assessments, there may be information of sufficient quality to consider another approach such as the use of both monitored and modeled exposure values in conjunction with human health hazard information (such as was utilized for the draft risk evaluation of HBCD). EPA has not yet completed its data evaluation phase of systematic review of the reasonably available literature and is not yet able to discern the fit-for-purpose approach for each High-Priority Substance risk evaluation.

In building exposure scenarios for the identified conditions of use, EPA reviews and analyzes reasonably available information. In considering potential current exposures from releases, EPA will consider what is known about the environmental fate parameters, physical-chemical properties, engineering release information, conditions of use and relevant monitoring data and modeling approaches in building exposure scenarios. EPA will consider reasonably available data and

information and use the best available science to determine whether to consider aggregate exposure for a particular chemical.

As a result of the Ninth Circuit Court of Appeals' decision in Safer Chemicals, Healthy Families v. U.S. EPA, 943 F.3d 397, 425 (9th Cir. 2019), EPA is no longer excluding legacy uses (i.e., circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) or associated disposal (i.e., ongoing disposals from legacy uses) from the definition of "conditions of use." Rather, when these activities are intended, known, or reasonably foreseen, these activities are considered uses and disposal, respectively, within the definition of "conditions of use." In reviewing the reasonably available information, EPA will consider specific uses that could represent exposures, and consider what is known about the environmental fate parameters and physical-chemical properties, including any relevant monitoring data and modeling approaches in building exposure scenarios based on the conditions of use. Please note that issues related to legacy uses and uses where a chemical is present as a contaminant or byproduct are discussed under "Legacy Uses" and "Impurities, Byproducts, and Contaminants."

Comment: One commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) asserted that a relevant subpopulation may be exposed to other chemicals contributing to adverse health effects in combination with the chemical substance under evaluation, and that exposure to other chemicals which contribute to the same adverse health effects as the chemical under review, causes the targeted subpopulation to be more "exposed and susceptible" to the adverse health effects posed by the chemical under review. The commenter also mentioned that EPA is required to consider such exposures when identifying and evaluating risks under TSCA section 6.

Response: EPA includes consideration of and identification of several PESS within the draft scope document (see Section 2.5). For each chemical substance, this may include woman of reproductive age within the workplace as well as woman of reproductive age who are consumer users and bystanders. PESS may also include infants, children, and the elderly, among others. Please note that additional issues related to PESS are discussed under "Potentially Exposed or Susceptible Subpopulations."

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0032) suggested that exposure to 1,3-butadiene likely co-occurs with other related industrial chemicals and encouraged EPA to investigate cumulative effects from co-exposures to chemicals that act in similar ways.

Comment: One commenter (EPA-HQ-OPPT-2018-0426-0019, EPA-HQ-OPPT-2018-0427-, EPA-HQ-OPPT-2018-0444-0027-0033, EPA-HQ-OPPT-2018-0446-0029), in regard to the "two Dichlorobenzenes (o-DCB and p-DCB) . . . [and] two Dichloroethanes (1,1-DCE and 1,2-DCE)," stated "In addition to the two isomers being assessed together in a cumulative assessment, they should also be assessed cumulatively, when having common conditions of use . . . and other exposures, toxicity endpoints, and metabolites and metabolic pathways, with tetrachloroethylene (PERC); 1,1,2,2-tetrachloroethane; trichloroethylene (TCE); 1,1,1-trichloroethane; and 1,2-dichloroethylene, as noted in Table 3-4 of the draft Trichloroethylene Risk Evaluation."

Comment: Another commenter (EPA-HQ-OPPT-2018-0426-0021) asserted that because exposure to 1,1-dichloroethane likely co-occurs with other related chlorinated solvents, cumulative effects from co-exposures to chemicals that act in similar ways should be considered. The commenter encouraged EPA to "investigate toxic activity exhibited by 1,1-dichloroethane that overlaps with similar activity exhibited

by related chemicals with potential co-exposures in order to assess the need for a cumulative risk assessment.”

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0038) encouraged EPA to adopt a cumulative assessment strategy and incorporate aggregate exposure estimates for phthalates via “a cumulative and/or read across risk assessment for the high-priority phthalates encompassing an expanded list of health endpoints” and “aggregate exposure from all sources when conducting risk assessments for phthalates in order to avoid underestimating the actual risk from phthalate exposure.” Other commenters (EPA-HQ-OPPT-2019-0131-0047, EPA-HQ-OPPT-2018-0504-0038) urged EPA to conduct a cumulative risk evaluation of the phthalates designated as High-Priority Substances.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) urged EPA to “combine the five phthalates listed as high priority with the two phthalates for which industry has requested risk evaluations into a single category and then conduct a cumulative risk assessment on this category. Category treatment is clearly warranted under section 26(c) of TSCA.” The commenter cited research and findings of the National Research Council (NRC): “because people are exposed to multiple phthalates at the same time, and phthalates contribute to one or more common adverse health outcomes, ‘a cumulative risk assessment should be conducted that evaluates the combined effects of exposure.’” The NRC further found that ‘Cumulative risk assessment based on common adverse outcomes is a feasible and physiologically relevant approach to the evaluation of the multiplicity of human exposures and directly reflects EPA’s mission to protect human health.’” Another commenter (EPA-HQ-OPPT-2019-0131-0043) stated “Butyl benzyl phthalate (BBP), Dibutyl phthalate (DBP), Dicyclohexyl phthalate (DCHP), Di-ethylhexyl phthalate (DEHP), and Di-isobutyl phthalate (DIBP) should be assessed as a group. And, to this group should be added Di-n-octyl phthalate (DnOP), Diisodecyl phthalate (DIDP), and Diisononyl phthalate (DINP). All three were on the 2014 TSCA Work Plan in the phthalate group, and risk evaluations for the latter two are underway as a consequence of manufacturers’ requests. In addition, several phthalates have been identified as endocrine disruptors. This mode of action should be addressed for all of the phthalates.” Another commenter (EPA-HQ-OPPT-2018-0434-0037) recommended that EPA should review the phthalates designated as High-Priority Substances as a category of chemicals, and along with DIDP and DINP, conduct a cumulative risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026, EPA-HQ-OPPT-2018-0426-0024, EPA-HQ-OPPT-2018-0427-0039, EPA-HQ-OPPT-2018-0428-0030, EPA-HQ-OPPT-2018-0465-0035, EPA-HQ-OPPT-2018-0433-0029, EPA-HQ-OPPT-2018-0434-0034, EPA-HQ-OPPT-2018-0501-0039, EPA-HQ-OPPT-2018-0503-0029, EPA-HQ-OPPT-2018-0504-0037) asked EPA to use a cumulative approach and “at a minimum, assess all common adverse health outcomes for the risk evaluations of phthalates and chlorinated solvents.”

Response: Risk evaluations for the individual phthalates, individual chlorinated solvents, and dichlorobenzenes will be performed as required under TSCA section 6(b)(4).

TSCA does not require EPA to assess common mode of action or common adverse outcomes. As described in the scope documents, EPA has begun the process of searching, screening and collecting the data and information for the scopes of the next 20 High-Priority Substances and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation,

EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions, including any conclusions regarding sentinel exposures, as appropriate, and risks to PESS. Because there are many individual factors that may influence susceptibility to exposure related health effects, susceptibilities may differ depending upon the chemical and its conditions of use. In its synthesis and integration of the evidence, EPA considers the mechanistic understanding of how a health outcome develops including whether differences in susceptibility may be explained by an analysis of toxicokinetic or toxicodynamic differences across life stages or populations. This information is considered in PESS analysis and informs uncertainty in risk estimation.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032) asserted that TCEP should be assessed in concert with the other structurally-related chlorinated phosphate ester flame retardants used in furniture foams, textiles, and paints and coatings (2-Propanol, 1-chloro-, 2,2',2''-phosphate (TCPP) and 2-Propanol, 1,3-dichloro-, phosphate (3:1) (TDCPP)). The same commenter requested that TBBPA be assessed in a group with the other structurally-related flame retardants used in plastics/printed circuit boards for electronics (TBBPA-bis(dibromopropyl ether), (TBBPA-bis(allyl ether), and TBBPA-bis(methyl ether). Another commenter (EPA-HQ-OPPT-2018-0458-0029, EPA-HQ-OPPT-2018-0462-0033, EPA-HQ-OPPT-2018-0476-0028) mentioned that exposure to TCEP, TPHP, and TBBPA co-occurs with other related halogenated and phosphate-based flame retardants.

Response: Under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, EPA conducts risk evaluations on existing chemicals identified as High-Priority Substances. TCPP and TDCPP were not identified as High-Priority Substances for the next twenty risk evaluations.

In regard to TBBPA, currently there are no isomers or similar chemicals being evaluated with TBBPA. Any articles containing data for TBBPA as well as other related chemicals will be used for future evaluations.

In regard to TPHP, EPA identifies phosphoric acid, triphenyl ester (TPP) as being synonymous with TPHP and will therefore review the available literature that mentions TPHP within the scope of the TPP assessment.

Physical-Chemical Properties and Fate

Comment: One commenter (EPA-HQ-OPPT-2018-0488-0030) asserted that ethylene dibromide is a dense liquid, as opposed to a colorless gas, as stated in the draft scope document for EDB. The same commenter also asserted that the draft scope document shows the imported quantity as 1 to 10 million pounds when in fact quantities for the past few years have not exceeded 1 million pounds, based on the commenter's market knowledge.

Response: EPA appreciates the correction to the physical form of ethylene dibromide and agrees that description of the physical form in the draft scope for risk evaluation is incorrect. EPA has corrected the physical form to describe ethylene dibromide as a "volatile, highly water-soluble liquid" to be consistent with the commenter's request, as well as in the "Proposed Designation of Ethylene Dibromide (CASRN 106-93-4)" as a High-Priority Substance for Risk Evaluation (Docket: EPA-HQ-OPPT-2018-0488-0011). The draft scope document for EDB and the imported quantities reported therein are in accordance with CDR data, current as of 2015. These data are self-reported by the manufacturers. EPA understands that said manufacturers may have more current data regarding quantities imported. In the event that new/more recent CDR is released during development of the risk

evaluations relating to EDB, EPA may revise the quantities imported in accordance with the more current CDR data.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0034) stated that phthalic anhydride is a white solid (lustrous needles) but is commercially available as flakes or as a molten liquid.

Response: EPA appreciates the suggested information for the background description.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0040) Stated that EPA correctly acknowledges the rapid hydrolysis of phthalic anhydride in typical environments. However, EPA failed to account for rapid hydrolysis in generating several key physical and chemical properties found in Appendix B-1. The commenter further notes that use of these erroneous values as inputs to the exposure models, such as ChemSTEER for occupational exposures, would result in gross overestimates of exposure.

Response: EPA has updated the phthalic anhydride final scope to more clearly define where reported properties and parameters refer to phthalic anhydride or phthalic acid. EPA plans to evaluate the risk associated with COUs for phthalic anhydride including exposure to its hydrolysis product (e.g., phthalic acid).

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0034) stated that phthalic anhydride hydrolyzes rapidly in water to phthalic acid (50% in 30 sec at pH 7 and 25 °C). Reports of phthalic anhydride in aqueous samples are likely to be analytical artifacts. The commenter further notes the toxicological effects also are expected to be different; for example, phthalic anhydride is classified as an inhalation and skin sensitizer, while phthalic acid is not a sensitizer based on animal studies.

Response: EPA agrees that phthalic anhydride rapidly hydrolyzes in water to form phthalic acid. EPA is evaluating hazard endpoints for both phthalic anhydride and phthalic acid for the phthalic anhydride risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0033) DEHP is not manufactured or imported in pellet form; it is a liquid under any normal use conditions. Compound containing DEHP could be imported in pellet form (i.e., a dry blend with polyvinyl chloride (PVC), plasticizer, and other additives is extruded into pellets).

Response: Please see Appendix E.1.1 of the scope document for di-ethylhexyl phthalate, where the importation of di-ethylhexyl phthalate is noted as either a pure liquid or a compound blended with PVC.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) noted that the approaches to vapor exposure for occupational non-users (ONUs), in Appendix F-1, and consumers, in Appendix G-1, appear to be inconsistent.

Response: While the two sections frame the potential inhalation pathway differently, this is not a fundamental inconsistency. The Occupational section is indicating that EPA does not foresee a pathway based on the low vapor pressure for this condition of use while consumer exposure notes that it will be evaluated further.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0035) stated that the draft scope document suggests that EPA will evaluate environmental releases and exposures of phthalic anhydride as part of

its analysis, including an assessment of impacts on ground and surface water and the PBT potential of the substance. The draft also notes, however, that releases to water represent 0.01% of total environmental releases from TRI facilities. Consequently, the manufacture and use of phthalic anhydride does not result in significant releases to surface water. In light of the substance's tendency to react in the presence of moisture, releases to groundwater through underground injection or other processes are highly unlikely to result in environmental exposures. Given its affinity to react with water, moreover, phthalic anhydride is neither persistent in the environment nor bioaccumulative. In addition, a PBT Assessment is not part of the EPA's final Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act (Risk Evaluation Rule).

Response: EPA acknowledges that phthalic anhydride readily hydrolyzes into phthalic acid and plans to consider this hydrolysis product within scope of the evaluation. EPA notes in Appendix C that phthalic anhydride has a half-life of 24.8 minutes based on first order hydrolysis of 4.29×10^{-4} /second at 25.1°C. Likewise, phthalic acid biodegrades by 85.2% over 14 days in activated sludge. As for bioaccumulation, phthalic acid has a bioconcentration factor of 3.2-3.4 and a bioaccumulation factor of 4.9. These properties are inconsistent with compounds that are PBTs, however, EPA is not tailoring pathways or analyses based on fate properties before conducting a systematic review of fate parameters.

In regard to water releases, EPA provides a brief summary of the information reported to TRI as totals, but site-specific information is reported through the TRI program. EPA considers the information reported through the TRI program to be one reasonably available source for the environmental release assessment, but EPA will consider all of the information gathered during systematic review. More detailed information on the data integration will be provided in the draft risk evaluation, at that time, EPA will have evaluated all reasonably available information to present a draft environmental release assessment.

Comment: A commenter (EPA-HQ-OPPT-2018-0458-0033) asserted that additional data and research is needed to supplement and appropriately evaluate the potential environmental fate and transport properties for TPP. The commenter stated "Although EPA is using more recent, information, such as for direct photodegradation, of the data sources cited to determine environmental fate and transport properties are from 1983 or earlier. Any data used to evaluate potential environmental hazards should reflect the current state of the science. The Agency should provide more details for how it will approach the use of any surrogate chemical data and address potential areas of uncertainty. In addition, as part of its environmental hazard assessment of TPP, EPA currently plans to consider a PBT assessment. Such an approach is not part of procedures for chemical risk evaluation under TSCA, and consideration of a PBT assessment should be removed from the final scope document."

Response: EPA considers reasonably available information and uses the best available science to evaluate existing chemicals under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. Therefore, all studies identified through public comment and the systematic review process will be considered. The use of surrogate chemicals to fill data needs is an acceptable approach should there be unacceptable or insufficient data for TPP. Persistent, bioaccumulative and toxic properties of all chemicals are considered for the risk evaluation because these chemical properties and characteristics impact both the exposure and hazard threshold established to assess environmental risk. EPA will not remove the consideration of these physical-chemical properties from the scope documents.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0041) asserted that "the use of the term "decompose" is not technically appropriate for the vast majority of formaldehyde resins. Additionally,

certain classes of formaldehyde resins are well known to not decompose. In the draft scoping document, the term “may decompose” is actually referring to the reversible reaction or hydrolysis of UF resins.” The commenter suggested that EPA “should remove this section as it generally only pertains to UF resins and there can be variations within this group of resins in the rate of hydrolysis. If this section is retained in the scoping document, EPA should at a minimum use the correct terminology to describe this reversible reaction chemistry in the final scoping document.”

Response: Based on the comment, EPA revised the section and uses the term “off-gas” in the scope document, which EPA intends to mean the release of formaldehyde gas into the air.

Exposure

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA cannot assume that an identified use as an intermediate reactant results in negligible release or exposure. Among the uses identified for 16 of the 20 high-priority substances is as a chemical “reactant” or “intermediate.” In some of the draft scopes for these chemicals, EPA implies that such uses entail negligible risk. The commenter stated “the chemical may remain in downstream reaction products or in the final product as a residual due to, for example, incomplete reactions. These residuals can be present in significant amounts in certain cases and there can be variation in the extent to which they are present over time, in different batches, or among different producers and processors. This variability should be considered when evaluating potential risk.” The commenter continued “chemicals used as reactants or intermediates must still be manufactured as well as typically stored, transferred, or distributed, all of which are activities that can lead to exposures—including to workers, whom TSCA expressly identifies as a “potentially exposed or susceptible subpopulation.” The commenter also stated “while companies often claim that intermediate or reactant chemicals are handled exclusively in ‘closed systems,’ this term is often loosely used and needs to be rigorously defined and supported by clear evidence establishing the absence of possible exposures and releases” and suggested that “[a]t a minimum, worker exposures should be assumed barring strong evidence to the contrary.”

Response: EPA agrees with the commenter. Exposures and releases may occur during the use of a chemical as an intermediate or reactant. EPA does plan to assess exposures and releases that can occur for the “Processing as a Reactant” condition of use. The magnitude, frequency, and duration of exposures and the associated routes of exposure will depend upon the physical-chemical properties of the chemical, worker activity patterns, and the conditions of use. Exposure scenarios will be developed based on these considerations and the reasonably available information, weight of the scientific evidence and best available science approaches. The scope document describes the conditions of use, PESS, hazards, and exposures that EPA plans to consider in this the risk evaluation. Risk conclusions will be presented in the risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0035) recommended that EPA release for public comment all the models and exposure scenario documents currently being used to support scope document development and subsequent TSCA risk evaluations and work with all industries to update and ensure the best available science is incorporated into these models. The commenter stated “EPA appears to have relied extensively on [Organisation for Economic Co-operation and Development (OECD)] Emission Scenario Documents (ESDs) as well as Generic Scenario Documents (GSDs) to model exposures where monitoring data is limited or unavailable.” The commenter expressed concern about “outdated assumptions” in EPA’s models and asserted that “a separate request for comment specific to all the scenario documents and models being used by EPA would bring a focus to better characterizing real world exposure potential.”

Response: The commenter correctly points out that EPA also utilizes exposure models and exposure scenario documents such as ESDs in preparing the occupational condition of use assessments for the risk evaluations. EPA's risk evaluation work does include identifying existing models, developing new models and identifying applicable exposure scenario documents. The models that EPA uses in risk evaluations are usually peer reviewed by a scientific committee or subject matter experts. For models that have not been peer reviewed, they will be reviewed during peer review of the applicable TSCA risk evaluation. Links to these models, GSDs, and ESDs are provided in Section 2.7 of the scope documents. The public will also have an opportunity to comment on the specific models and scenarios used during the comment period following publication of the draft risk evaluations.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0022) asserted that the draft scopes fail to identify all reasonably available information about exposure. The commenter stated "TSCA requires EPA to conduct risk evaluations based on 'reasonably available' information. EPA defines this term to include not only 'information that EPA possesses' but also information that EPA 'can reasonably generate, obtain, and synthesize for use in risk evaluations.' TSCA also provides EPA with broad authority to require the production or generation of exposure and toxicity data. If such data already exists, EPA can require its production under TSCA Section 8 or issue subpoenas for such information under TSCA Section 11. If such data does not presently exist, EPA can order additional workplace monitoring under TSCA Section 4."

Response: One key objective in developing TSCA risk evaluations is to conduct a systematic review of reasonably available data, models, and exposure/release scenario documents that can be used in the evaluation. As presented in the scope documents, the distribution of information resulting from full-text literature screening are found in information evidence tables. These tables help EPA identify key data needs, and EPA will develop strategies to fill these data needs to the extent possible. The commenter makes a reasonable suggestion for EPA to consider use of its TSCA authorities to fill data needs.

In accordance with 40 CFR 702.41(c), each draft scope document includes a description of the reasonably available information EPA plans to use in the risk evaluation. EPA is not required to publish or provide in full all of such information.

In regard to the suggestion to conduct broader outreach to obtain reasonably available information, such issues are discussed in the "Information Considered and Additional Data-Gathering" section of this document.

Comment: A commenter (EPA-HQ-OPPT-2018-0488-0031) remarked on the following statement in Section 2.3.7 of the Draft Scope of the Risk Evaluation for Ethylene Dibromide: "Populations living in areas near oil refineries, chemical manufacturing plants, and plastic and rubber factories where ethylene dibromide is manufactured or used would be expected to have higher exposures." The commenter stated "Despite acknowledging that people living near certain industrial and waste facilities have 'greater exposure' than the general population to chemicals that present well-documented hazards (meaning they face 'greater risk than the general population of adverse health effects,' precisely what TSCA defines as a 'potentially exposed or susceptible subpopulation'), the draft scopes inexplicably treat these duration- and location-specific 'greater exposures' as general population exposures."

Response: TSCA directs EPA to identify "potentially exposed or susceptible subpopulations," defined as "a group of individuals within the general population identified by the [EPA] Administrator who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of

adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly” (15 U.S.C. § 2602). As a result, EPA is considering reasonably available data relevant to chemical exposures from specific conditions of use to populations who reside near the “fence line,” and thus may receive a relatively greater exposure in comparison to the general population. EPA encourages the public including stakeholders to provide data, comments and suggestions. Please note that environmental justice issues are discussed under the “Environmental Justice” section of this document.

Comment: One (EPA-HQ-OPPT-2018-0451-0031) requested that EPA consider spills, leaks, fires, and explosions at facilities releasing and/or transferring high-priority chemicals as conditions of use, and stated “Incidents such as these explosions, leaks, spills, and equipment failures have been found to be reasonably foreseeable under other laws in similar contexts. For example, EPA and regulated industries recognize that inadvertent releases of hazardous air pollutants occur and are inevitable. In addition, the interpretation and implementation of the National Environmental Policy Act (‘NEPA’) shows that, in the realm of environmental law, ‘reasonable foreseeability’ includes accidental releases. Indeed, federal guidance for preparation of NEPA analyses acknowledges that accidents may be foreseeable. TSCA risk evaluations provide comprehensive information to support EPA’s risk determination and require in-depth analysis of reasonably foreseeable future conditions in order to provide meaningful information to support agency decision-making. This reading of reasonably foreseen to include accidental circumstances that occur during conditions of use is further confirmed by other language in the amended TSCA. The statute requires that the process for prioritizing risk evaluations ‘shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water).’”

The commenter also provided information about petrochemical facilities in Texas and Louisiana and recommended that to obtain information about spills, leaks, fires, explosions, and other accidents involving the TSCA high-priority chemicals—including their frequency—EPA must affirmatively ask all manufacturers, processors, distributors, and disposers/recyclers of these chemicals to produce all information in their possession about environmental releases (including leaks, spills, discharges, and emissions), misuses, and accidents involving these substances, including an estimate of the amount and the frequency of releases, misuses, and accidents over the last decade.

Finally, the commenter mentioned that Texas and Louisiana facilities known to handle 1,3-butadiene have a documented history of spills, leaks, fires and explosions.

Response: Spills, leaks, and releases from accidents (including fires and explosions) generally are not included within the scope of a TSCA risk evaluation. First, EPA does not identify spills, leaks, or accidental releases as “conditions of use.” EPA does not consider spills, leaks, or accidental releases to constitute circumstances under which the 20 High-Priority Substances are manufactured, processed, distributed, used, or disposed of, within TSCA’s definition of “conditions of use.” Congress specifically listed discrete, routine chemical life cycle stages within the statutory definition of “conditions of use” and EPA does not believe it is reasonable to interpret “circumstances” under which those substances are manufactured, processed, distributed, used, or disposed of to include uncommon and unconfined spills, leaks, or accidental releases for purposes of the statutory definition. Further, EPA does not generally consider spills, leaks, and accidental releases to constitute “disposal” for purposes of identifying a COU in the conduct of a risk evaluation.

In addition, even if spills, leaks, or accidental releases could be considered part of the listed life cycle stages of the 20 High-Priority Substances, EPA has “determined” that spills, leaks, and accidental releases are not circumstances under which those substances are 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 therefore exercises its discretionary authority under TSCA section 3(4) to exclude spills, leaks, and accidental releases from the scope of the risk evaluation for the 20 High-Priority Substances. 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 (82 FR 33726 (July 20, 2017)), 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, leaks, and accidental releases as part of risk evaluation, which could make the conduct of risk evaluations untenable within the applicable deadlines, spills, leaks, and accidental releases are determined not to be circumstances under which the 20 High-Priority Substances are 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, leaks, and accidental releases of the 20 High-Priority Substances 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, leaks, and accidental releases, were not intended to be the focus of TSCA risk evaluations. And, as noted in the preamble to the Risk Evaluation Rule (82 FR 33726 (July 20, 2017)), 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, leaks, and accidental releases of the 20 High-Priority Substances to be COUs.

Second, even if spills, leaks, or accidental releases 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 evaluations for the 20 High-Priority Substances. 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 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 (82 FR 33726 (July 20, 2017)), 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, EPA has found that exposures of some of the 20 High-Priority Substances from spills, leaks, and accidental releases fall under the jurisdiction of RCRA (see 40 CFR 261.33(d) (defining in part a hazardous waste as “any residue or contaminated soil, water or other debris resulting from the cleanup of a spill into or on any land or water of any commercial chemical product or manufacturing chemical intermediate having the generic name listed [40 CFR 261.33(e) or (f)], or any residue or contaminated soil, water or other debris resulting from the cleanup of a spill, into or on any land or water, of any off-specification chemical product and manufacturing chemical intermediate which, if it met specifications, would have the generic name listed in [40 CFR 261.33(e) or (f)]”); 40 CFR 261.33 (f) (listing High-Priority Substances)¹). As a result, EPA believes it is both reasonable and prudent to tailor the TSCA risk evaluation for the High-Priority Substances by declining to evaluate potential exposures from spills, leaks, and accidental releases, rather than attempt to evaluate and regulate potential exposures from such spills, leaks, and accidental releases under TSCA.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) asserted that the draft scopes fail to adequately evaluate oral exposure routes for workers and that EPA’s approach of generally not evaluating occupational exposures through the oral route is a fundamental analytical flaw. The commenter stated “oral exposure can happen unintentionally in the workplace, as “[w]orkers may inadvertently transfer chemicals from their hands to their mouths, ingest inhaled particles that deposit in the upper respiratory tract or consume contaminated food.” Despite EPA’s stated plans to ignore many of those exposures, studies have shown that as many as one in six workers can inadvertently ingest hazardous substances through activities like biting their nails, touching their faces, or eating in an area where chemicals dusts can contaminate their food. The amount of a material a worker consumes can also ‘increase for substances that are easily transferred to the hand and are either not visible . . . or are not viewed by the worker as being hazardous.’ Further, ingestion is a longer-term concern, as ‘uptake

¹ The following High-Priority Substances are listed at 40 CFR 261.33(f): *p*-Dichlorobenzene (106-46-7; U072); 1,2-Dichloroethane (107-06-2; U077); *trans*-1,2-Dichloroethylene (156-60-5; U079); *o*-Dichlorobenzene (95-50-1; U070); 1,1,2-Trichloroethane (79-00-5; U227); 1,2-Dichloropropane (78-87-5; U083); 1,1-Dichloroethane (75-34-3; U076); Dibutyl phthalate (1,2-Benzene-dicarboxylic acid, 1,2-dibutyl ester) (84-74-2, U069); Di-ethylhexyl phthalate - (1,2-Benzene-dicarboxylic acid, 1,2-bis(2-ethylhexyl) ester) (117-81-7; U028); Ethylene dibromide (106-93-4; U067); Formaldehyde (50-00-0; U122); and Phthalic anhydride (85-44-9; U190).

may continue for hours or days after work as a result of nail biting or hand-to-mouth contact with unwashed skin.’ Particularly for persistent, bioaccumulative, and toxic chemicals, these ingestion exposures add up and contribute to workers’ risks.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that the draft scopes suggest EPA plans to largely ignore the oral route of exposure for the 20 high priority chemicals, just as the agency did for the first 10 chemicals it evaluated. The commenter urged EPA to address the oral route of exposure in order to comprehensively assess the risk of these chemicals and stated “EDF has not examined all of the draft scopes for their treatment of the oral route of exposure. However, it appears that for most, if not all, of the 20 chemicals, EPA plans largely to exclude the oral route of exposure for:

- workers (e.g., “EPA generally does not evaluate occupational exposures through the oral route;” p-dichlorobenzene draft scope, p. 31),
- consumers (e.g., absence of ingestion/oral route for consumers in Appendix G of p-dichlorobenzene draft scope, pp. 97-98); and
- the general population (e.g., “The following pathways will not be evaluated: ambient air, *drinking water*, ambient water, disposal, sediment, and soil,” p-dichlorobenzene draft scope, p. 50, emphasis added).”

With regard to workers, the commenter agreed that EPA must consider workers’ incidental ingestion of inhalation dust (though it is unclear for how many conditions of use EPA will assess this route), EPA must also consider hand-to-mouth behaviors leading to direct chemical or dust ingestion in the workplace. With regard to consumers, the commenter stated “it appears EPA plans largely to ignore potential oral exposures. However, for at least TBBPA and TCEP, EPA indicates that it will consider children’s mouthing of articles for certain conditions of use as well as ingestion of dust for most consumer conditions of use of these two chemicals.” The commenter also stated “There is ample evidence demonstrating that flame retardants present in furniture, electronics, and other products are released and end up in house dust, which can be a source of exposure not only via inhalation but also via oral exposure. As such, mouthing of articles and ingestion of dust are important routes of exposure, especially for young children who frequently put objects in their mouths and crawl on the floor. EPA’s inclusion of these routes of exposure for TBBPA and TCEP needs to be extended to any of the other 20 high-priority chemicals found in finished household products that may be mouthed or that can be released into household dust. To the extent that EPA decides to exclude the oral route of exposure in the final scope for any chemical, EPA should provide empirical data supporting its decision for each subpopulation.”

Response: EPA acknowledges that oral exposures are a potential route for workers and agrees that hand-to-mouth and ingestion of dust particles can be sources of occupational oral exposure. EPA has identified chemicals during the scoping phase that will be evaluated for this route based on their physical-chemical properties. However, EPA does not currently have a methodology for quantitatively assessing occupational oral exposure. As described in the draft scope documents, EPA will consider oral exposure on a case-by-case basis considering all reasonably available data and information.

The consumer exposure routes as presented in each of the scope documents are dependent on the chemical, the physical-chemical properties and the corresponding conditions of use. In addition, each scope and subsequent risk evaluation is “fit-for-purpose” and considers reasonably available information for each chemical. For example, volatile chemicals that are not present in articles or found

in house dust, are not expected to have a significant oral route of exposure via mouthing. As the commenter noted, chemicals such as TBBPA and TCEP are expected to be in articles and therefore present an oral route of exposure, as identified in the consumer conceptual model. Should data or information be presented through public comment regarding other chemicals' presence in articles that could be mouthed by children, EPA will adjust the respective conceptual models for the risk evaluations to include the oral route of exposure for the risk evaluations.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) encouraged EPA to “consider the maximum or 99th percentile when calculating risk. Maximum values can skew considerably higher than the median or 95th percentile. If an exposure scenario is chosen that doesn't account for the most exposed individuals, many individuals could be left unprotected from 1,1-Dichloroethane's effects. For chemicals with ubiquitous exposures the highest-exposed 5% of the US population represents 15 million people who would face risks above high-end estimates in exposure estimates. In many environmental chemical exposure distributions in the general population, the maximum or 99.9th percentile exposures can be many times higher than the 95th percentile, so the magnitude of the corresponding excess risks are also potentially similarly skewed.”

Response: EPA acknowledges that exposures (and any subsequent risk) vary due to differences among individuals, populations, spatial and temporal scales and other factors and strives to present both a central tendency and a high-end estimate of exposures in characterizing exposure for the risk evaluation. In estimating exposures for the risk evaluation, EPA utilizes guidance as provided in EPA's *Guidelines for Human Exposure Assessment (U.S. EPA, 2019)*, which defines “High-End” as the 90th to 99.99 percentile exposure.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) commented on the likelihood of bystander exposure via the oral and dermal routes, stating: “In most cases related to the assessment of consumer and bystander exposures from consumer uses, EPA is proposing to assess the potential exposure to consumers by the inhalation and dermal routes and occasionally by the oral route, but only by the inhalation route for bystanders. We would argue that there are likely to be many instances in which the bystander is not simply positioned passively several feet away during the use activity but is interacting much more actively—perhaps touching the treated article and then engaging in hand-to-mouth behavior. Given this likelihood, we would recommend that bystander exposure via dermal and oral routes be incorporated into the risk assessments.”

Response: EPA's approach for chemical risk evaluations is to assess exposures, hazards and risks for the chemical being evaluated under the conditions of use. Each condition of use is different, each consumer product is utilized differently, and it is possible that bystanders may be involved in a variety of behaviors while the user is simultaneously using a specific chemical product. In building exposure scenarios, EPA considers the activity patterns of the consumer and bystander, in addition to exposure factors such as life stage and associated behaviors. As described in the draft scope documents, EPA may consider oral and dermal exposure on a case-by-case basis.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted EPA cannot dismiss routes of exposure based on qualitative analysis using only physical-chemical properties or on models with no uncertainty analysis. The commenter criticized EPA's approach of relying solely on physical-chemical properties to dismiss exposure pathways and utilizing modeled values without conducting any uncertainty analysis. The commenter stated that “Both approaches have been criticized by the SACC as insufficient. Among other concerns, the SACC noted

‘that it's incorrect to assume zero concentration in any phase based on equilibrium coefficients’ and ‘uncertainty in the estimates presented for environmental exposures needs to be addressed.’” The commenter stated “how and how quickly chemicals partition in the environment is dependent on environmental conditions” and that “[b]y assuming equilibrium, EPA is ignoring chemicals of concern that can occur in high concentrations in different environmental compartments prior to reaching equilibrium, if it is reached at all.”

With respect to the second approach, the commenter asserted that while models based on physical-chemical properties of chemicals can be useful in providing a preliminary understanding of both hazard and exposure, they are inappropriate for dismissing exposure and risk outright, especially without a corresponding and supportive uncertainty analysis to understand the sensitivity of the conclusions to the model. The commenter also criticized EPA’s use of EPI Suite™ for estimated p-chem values, asserting that physical-chemical property models in EPI Suite™ lack transparency in performance and applicability. Finally the commenter stated “If EPA wishes to use qualitative approaches involving extrapolation from physical-chemical and fate properties (many of which are modeled rather than measured), to dismiss exposure pathways as ‘unlikely,’ the agency must at the very least include an uncertainty analysis to elucidate what level of confidence can be carried over into the models on which it relies.”

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034) asserted that EPA’s risk evaluation must consider all exposure pathways and objected to the proposal “to exclude from consideration exposures via the ambient air or drinking water pathways, without determining the magnitude of the exposures or their contribution to risks for potentially exposed or susceptible subpopulations.” In regard to 1,2-dichloroethane, the commenter outlined concerns PESS exposures associated with ambient air and drinking water pathways and stated “EPA cannot properly identify the potentially exposed or susceptible subpopulations if it ignores the pathways which cause subpopulations to be identified as such. Accordingly, EPA’s proposed approach is directly contrary to the statutory definition of potentially exposed or susceptible populations, and thus violates EPA’s cornerstone obligation to consider and protect such subpopulations in the risk evaluation process.” The commenter cited *Safer Chemicals Healthy Families v. U.S. EPA*, 943 F.3d 397, 419 (9th Cir. 2019), which concluded that EPA’s regulations in the Risk Evaluation Rule “unambiguously do not grant EPA the discretion” to exclude conditions of use from a risk evaluation. The commenter argued “EPA’s decision to ignore exposures at the risk evaluation stage based on the existence of EPA’s air and drinking water programs ignores the plain language of Section 9 of TSCA” because “EPA’s approach would read Section 9(b) out of the law, since coordination with other EPA-administered laws at the stage identified in that provision would never be needed if the exposures are disregarded during the earlier risk evaluation.” The commenter also stated “EPA’s approach also ignores the actual exposures experienced by vulnerable populations due to chronic violations of the programs upon which EPA mistakenly relies. As demonstrated below, for the . . . identified potentially exposed or susceptible subpopulations, drinking water providers frequently violate applicable program requirements.”

Response: EPA reviews all reasonably available information and considers a combination of chemical-specific information on environmental releases, physical-chemical properties, fate and transport in environmental media, along with modeling and modeling information to evaluate exposure pathways. If EPA determines, in integrating this information in the risk evaluation, that there is insufficient data to quantify the exposures, EPA may qualitatively characterize exposures. This is performed on a per-chemical basis. EPA agrees that uncertainty analysis is an important aspect of exposure assessment, as documented in EPA’s *Guidelines for Human Exposure Assessment* ([U.S. EPA, 2019](#)).

As explained in more detail in Section 2.6 of the final scope documents, 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 each of the 20 High-Priority Substances using authorities in TSCA sections 6(b) and 9(b)(1).

Comment: One Commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA must fully account for exposure through food consumption. The commenter stated "From our review of the 20 draft scopes, when EPA considered contaminated food as a source of exposure, the agency categorized it in Section 2.3.7 on 'General Population Exposures' or Section 2.3.5 on 'Occupational Exposures.' Food is not mentioned in Section 2.3.6 on 'Consumer Exposures.' It is not at all clear why EPA does not consider and classify exposure through food to be a consumer exposure; food is clearly consumed by people and constitutes a consumer product for the vast majority of people. Further, in many cases, EPA ultimately ignores food as a source of exposure in its Conceptual Models and supporting Appendices, even when food as a source of exposure is mentioned elsewhere in the draft scope." The commenter asserted that food and oral route of exposure must be considered in an occupational setting and noted "While in some cases a worker may not consume food or drink while directly engaged in a work task, most workers in and around where these chemicals are manufactured, processed or used will take breaks to use the restroom, eat lunch, and engage in other such activities. Some workers may well eat or drink while actively working. Workers may not carefully wash their face and hands or change out of their contaminated clothes for each break or at the end of the day. And they may touch surfaces on which a chemical, especially if it is not volatile, may settle. During each of these activities, workers may transfer a chemical to food they then consume or otherwise engage in hand-to-mouth activities that result in ingestion." The commenter asserted that models developed by EPA and other federal agencies estimate the exposure to a chemical from food and "provide detailed, statistically representative, exposure estimates for a diverse set of demographic factors, especially for vulnerable subpopulations." The commenter recommended that EPA investigate using these models. The commenter also recommended that EPA seek out information on chemicals in food from foreign authorities (e.g., European Food Safety Authority, Food Standard Agency of Australia New Zealand, and the Food Standards Agency of the United Kingdom). The commenter asserted that the presence of chemicals in food must be considered in exposure assessments and noted "nine draft scopes either identify foods in addition to fish as exposure sources (e.g., root crops, mother's milk), or identify food or diet more generally as a source – yet none of these indicate EPA will evaluate exposure to any foods other than fish. EPA provides no explanation for not doing so." The commenter recommended that EPA actively seek out data on whether any of the 20 High-Priority Substances are present in food, and if so, must fully assess exposure potential via food in three different exposure scenarios:

1. When the environment is a source of contamination – The presence of any of the 20 chemicals in food may well be due to environmental contamination; such exposure clearly falls under EPA's authority and mandate under TSCA and must be included in the scope of the risk evaluation.
2. When the source of contamination is not discernable – Just as detection of a chemical through biomonitoring indicates exposure even if the source of that exposure is not known,

exposures due to the presence of a chemical in food need to be accounted for. This may well be the situation for many of the 17 high-priority chemicals for which the U.S. Food and Drug Administration (FDA) has authorized limited use in food contact articles *and* that are also released into the environment.

3. When an FDA authorized use is the source of the contamination – Some occurrences of a chemical in food may be able to be directly attributable to a source that falls outside TSCA’s jurisdiction. For example, leaching of a chemical from food packaging, or its use as a food additive, are sources that fall under the jurisdiction of FDA. Even if such a food use of a chemical falling under FDA is the source, such exposures must still be considered at least as background contributors to the overall risk evaluated under TSCA.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA should identify and include conditions of use that are analogous to those for food uses of the chemicals but fall under TSCA and that the draft scopes for the five ortho-phthalates contain listings of uses approved under FDA regulations are incomplete. The commenter recommended that EPA needs to account for the fact that FDA authorizes additional uses of chemicals in response to notices rather than issuing regulations and encouraged EPA to use the FDA search tool to identify all FDA-authorized used for these chemicals. The commenter noted identifying likely uses authorized by FDA for 17 of the 20 chemicals covered by the draft scopes using that search tool. The commenter stated “While we understand that a food additive use of FDA-authorized food additives is not within the jurisdiction of TSCA . . . many of the food-related uses could extend to use in other consumer and industrial products that do fall under TSCA” and “EPA should include these uses in the final scopes unless it has evidence they are limited to food.”

Response: EPA agrees that inadvertent transfer of chemicals to food and then the worker’s mouth is another potential source of occupational oral exposure. As described in the draft scope documents, EPA will consider oral exposure on a case-by-case basis. EPA will consider reasonably available data and information that can be used for developing approaches to assess occupational oral exposure. However, EPA notes that Occupational Safety and Health Administration (OSHA) regulations generally prohibit eating in the workplace, so eating should result in minimal exposures.

TSCA risk evaluations are fit-for-purpose. EPA plans to consider food as a source of chemical exposure insofar it is related to a condition of use. As the commenter mentions, food and food additives are outside the jurisdiction of EPA, and instead fall under the jurisdiction of FDA. TSCA’s definition of “chemical substance” excludes “any food, food additive, drug, cosmetic, or device (as such terms are defined in Section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037, EPA-HQ-OPPT-2018-0438-0054) questions the Agency’s use of an RME metric to assess exposure risk and stated “EPA guidance states that the assessor may derive a high-end estimate of exposure by using maximum or near maximum values for one or more sensitive exposure factors, leaving others at their mean value. Therefore, RME is not the worst-case exposure and a worst-case exposure analysis was not required by EPA.”

Response: The Agency appreciates this comment, but will not revise the scoping documents and will consider this for the risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) agreed with EPA's decision to exclude oral exposures for consumers and stated "there is no liquid 1,3-butadiene in tires."

Response: EPA appreciates this feedback regarding the risk evaluation process.

Comment: One commenter (EPA-HQ-OPPT-2018-0459-0034) noted that a review of the SDS referenced in the phthalic anhydride scope suggests that some products such as primers or varnishes contain phthalic anhydride in their formulations.

Response: EPA plans to investigate this issue further in the risk evaluation on whether these types of products contain residual amounts of phthalic anhydride or its hydrolysis product versus reaction products made from phthalic anhydride.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0034) stated that it is unclear whether phthalic anhydride is present in a number of types of products or if it is a reactant (i.e., consumed) to produce other materials. The agency must distinguish between its use as an intermediate or reactant and its direct use in industrial, commercial, or consumer formulations.

Response: EPA agrees with the comment and plans to investigate further in the risk evaluation to gather information on the % residual of phthalic anhydride or its hydrolysis product (if any) in commercial products that contain reaction products produced from the use of phthalic anhydride as an intermediate.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0034) stated that it is known that phthalic anhydride can be formed as an analytical artifact during gas chromatographic analysis.¹ Reported concentrations in environmental samples, particularly in water, must be reviewed carefully. (SIDS, 2005).

Response: Data quality evaluation is an integral step in the systematic review process that will be conducted for the draft risk evaluation before integrating biomonitoring data into an evaluation. The comment is noted and will be considered as part of the subsequent data quality evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0459-0040) stressed "while it is possible for children, women of reproductive age, and workers to come into contact with alkyd-based painted products or use such coatings themselves, it is not possible to have contact with [phthalic anhydride] from such use. In paint and coatings manufacturing, there is no possibility of exposure to [phthalic anhydride], as it no longer exists by the time an alkyd resin is used as a raw material."

Response: Regarding the paint and coatings manufacturing comment, EPA recognizes that phthalic anhydride is used primarily as an intermediate to make other chemical products. For this type of use as a reaction intermediate, we agree that phthalic anhydride would be expected to be reacted away and not become part of the reaction product, which could then become part of commercial products such as coatings.

We intend to investigate this further in the risk evaluation to gather information on the % residual of phthalic anhydride or its hydrolysis product (if any) in commercial products that contain reaction products produced from the use of phthalic anhydride as an intermediate. A statement of this point was added to the Process Description in E.1.3.1.

Comment: One Commenter (EPA-HQ-OPPT-2018-0433-0033) noted that some studies report the presence of DEHP in human matrices. Since DEHP and other ortho-phthalates are quickly metabolized, it is likely that the presence of DEHP (i.e., unmetabolized) in human tissues, urine, etc., is due to analytical artifacts and should be viewed as invalid (e.g., McKee, 20041 as referenced in NTP CERHR, 20062).

Response: The information provided in the scope documents includes information presented in the Proposed Designation documents, which noted data may be reasonably available for later integration. Data quality evaluation is an integral step in the systematic review process that will be conducted for the draft risk evaluation before integrating biomonitoring data into an evaluation. The comment is noted and will be considered as part of the subsequent data quality evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0504-0043), in regard to dicyclohexyl phthalate, encouraged EPA to review the logic behind planning to evaluate exposure scenarios under the category “Emissions to Air.” The commenter stated “on page 66 of the draft scope document (Appendix F), the rationale behind planning not to evaluate worker inhalation exposure is “Due to dicyclohexyl phthalate's vapor pressure (VP) ($VP = 8.69 \times 10^{-7}$ mm Hg) at room temperature, potential for vapor generation is low.” We believe this rationale also applies to the “Emissions to Air” category, and these scenarios should be dropped from plans to evaluate. Deposition of the substance beyond the immediate handling area is unlikely due to the very low vapor pressure.”

Response: It appears that the commenter interpreted “emissions to air” to mean vapor releases. EPA agrees that vapor emissions are unlikely, but we do plan to investigate the effects of elevated temperatures. Emissions to air may also include particulate and mists/aerosols. Since dicyclohexyl phthalate is used in paints and adhesives, there may be mist releases to air during spray application. Additionally, since dicyclohexyl phthalate is solid, EPA will also consider the potential for particulate releases to air.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0033, EPA-HQ-OPPT-2018-0459-0034) asserted human biomonitoring data based on urinary metabolites mentioned are important in determining “background” exposure to the general human populations and that general exposure should not be ignored as part of the overall risk assessment.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0040) urged EPA to address the uncertainty associated with using models suited for indoor settings in outdoor settings, as it is not appropriate to use unadjusted indoor models as a worst-case outdoor exposure estimate. The commenter stated “While these are commonly used models in risk assessment, special consideration should be made when using these models to estimate exposures in an outdoor setting like that of an EDC production facility. In general, the well-mixed box model underestimates exposures close to the emission source, therefore, the near field-far field model is used to simulate breathing zone and area exposures. Both the well-mixed box model and the near field-far field model are simple models ideal for indoor spaces, and therefore do not simulate imperfectly mixed air or wind direction, key characteristics in outdoor settings. Therefore, modeled occupational exposures using this methodology are unlikely to represent conditions of use performed outdoors.” The same commenter suggested the use of a probabilistic risk assessment, stating “Probabilistic methods have been used to address the variability and uncertainty associated with risk assessments. A probabilistic assessment, such as a Monte Carlo analysis, can evaluate the inherent variability of model parameters and the uncertainty associated with model assumptions.”

Response: EPA acknowledges that certain box models and near-field/far-field models are intended to estimate exposure in indoor settings. EPA will consider the most applicable model for each exposure scenario when performing exposure modeling and will address any uncertainty in the models used. In addition, EPA will consider other data, including human biomonitoring data, as applicable as part of the overall risk evaluation.

In regard to probabilistic methods, EPA appreciates this comment and will consider these issues, including a sensitivity analysis, on a chemical-by-chemical basis when performing probabilistic assessments for the 20 High-Priority Substances. Where appropriate, EPA may perform targeted searches on model input parameters to construct exposure scenarios that are anchored in the real-world use of chemicals. EPA also welcomes additional data and information on the aforementioned parameters, such as ventilation rate and mixing factor, that represent current industrial practices.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0040) recommended EPA consider an occupational dermal exposure assessment, stating “While not explained in the draft scope, based on prior assessments, [the commenter] assumes that occupational dermal exposures will be modeled under steady-state conditions via the Dermal Exposure to Volatile Liquids (DEVL) model. Specifically, a fraction absorbed into the stratum corneum will be estimated assuming a steady-state condition. It may be likely that dermal exposure in an occupational setting will not reach a steady-state condition, such that a fraction of EDC absorbed cannot be assumed under a steady-state condition. Therefore, the estimated dermal exposure will be an overestimation of realistic conditions.”

Response: EPA plans to evaluate reasonably available dermal exposure data and information during systematic review, including chemical-specific dermal exposure data, experimental studies, and applicable exposure models. EPA may also consider refining existing EPA models, such as the Dermal Exposure to Volatile Liquids model, on a case-by-case basis, to improve the accuracy of its assessments.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028) provided previously submitted comments on the Agency’s New Chemicals program (Comments on EPA’s Working Approach to Making New Chemicals Determinations, EPA-HQ-OPPT-2019-0684 (Feb. 18, 2020)), regarding conditions of use potentially involving releases to water. The commenter mentioned studies describing the operational conditions and environmental exposure scenarios during the formulation of fragrance preparations and their incorporation into household and personal care products, as well as the commenter’s explanation of “how EPA’s default assumptions are inconsistent with the economic realities of the fragrance industry, as fragrance ingredients and compounds are highly valuable and extremely costly.”

Response: EPA plans to consider this issue during risk evaluation and to conduct its risk evaluation of 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB) using reasonably available information and best available science. EPA also plans to consider its 2014 risk evaluation of HHCB for its upcoming full assessment of HHCB.

Consumer Exposure

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) provided a series of comments related to exposure pathways in the draft scope document for 1,3-butadiene; in particular, the commenter noted its likelihood, or lack thereof, for consumer exposure:

1. 1,3-Butadiene is not sold directly to consumers, rather as shown on Figure 2-7 in the draft scope, the substance is used directly by industrial processors. Given the high reactivity of butadiene in the formation of various intermediates such as rubber or plastic polymers or as a raw material for the manufacturing of other chemicals such as adiponitrile, nearly all of the monomer is converted or removed through the processing. The EPA should refer to the residual amounts of 1,3-butadiene reported by IISRP and other intermediate producers in the butadiene supply chain to understand the available mass of the substance in finished consumer products.
2. As stated previously, butadiene is not directly used by consumers, rather the potential for exposure is based on its residual concentration in a product made from butadiene-based polymers or other intermediates. EPA should revise the descriptions of consumer use throughout the draft scope to reflect that any potential for butadiene exposure from use of consumer products would only arise from its potential presence as a residual monomer.
3. 1,3-Butadiene in liquid form occurs when the gas is placed under pressure at low temperatures. Given that 1,3-butadiene's presence in a finished consumer product would be as a residual under ambient pressure and temperature, it would not be available for dermal contact in a liquid form.

Response: In regard to items 1 and 2: Although 1,3-butadiene is not sold directly to consumers, EPA considers the possibility of consumers' ability to acquire it through alternative means or gray market. EPA acknowledges that mono butadiene may only be present in residual amounts in plastics and rubber products. These residual amounts or weight fractions are important parameters in the consumer exposure modeling. If the residual amounts are indeed insignificant, the model will assist EPA to take into account small amounts known to be found in consumer products.

In regard to item 3: Thank you for noting this. EPA has removed dermal exposures from consideration in the final scope document due to 1,3-butadiene's high volatility. Inhalation has now been identified as the only potential route of concern for consumers and bystanders.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) suggested that the potential for consumer exposure to 1,3-butadiene in finished tires stems from the unlikely presence of residual 1,3-butadiene monomer confined in the synthetic rubber polymer used in compounds to manufacture tires. USTMA urges EPA to review the residual 1,3-butadiene monomer information submitted by [EPA-HQ-OPPT-2018-0451-0027]. The commenter suggested that such data show that 1,3-butadiene as a monomer is estimated to be present at <50 ppb in the two primary synthetic polymers used in tire manufacturing. The commenter stated "if present, 1,3-butadiene as a residual monomer comprises an insignificant mass in the overall composition of a tire."

Response: EPA plans to evaluate plastic and rubber products that incorporate the use of 1,3-butadiene (monomer) in polymer manufacturing. However, the monomer of 1,3-butadiene is in scope – not polybutadiene. Therefore, this scope will investigate risk to 1,3-butadiene (monomer) exposure according to consumer use of plastics and rubber products.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) suggested that the "vast weight of the evidence demonstrates that the potential for dermal exposure to 1,3-butadiene during consumer use of tires produced from synthetic rubber is negligible." The comment raised concerns regarding the assessment of consumer exposures and stated that the "vast majority of drivers have their tires installed by the retail tire dealer, so the consumer does not touch the tire. Dermal exposure to a tire is assumed to

occur to a consumer when the driver of the passenger car/light truck, at most once monthly, checks the air pressure on all four tires (as recommended by the tire industry) beginning from 16 years old to 70 years old, e.g. exposure occurs at 12 times per year for 54 years. There is data suggesting that the average consumer checks their tire pressure less frequently than once of month. In any case, the lifetime exposure to a consumer is very low compared to workers.”

Response: Consumer dermal exposure to 1,3-butadiene is no longer in scope as this exposure route has been determined to be unlikely due to its physical-chemical properties.

Comment: A commenter (EPA-HQ-OPPT-2018-0433-0033) stated that exposure through dust is discussed in several sections of the scope document. Estimates of exposure based on DEHP content in dust may overestimate actual exposure. Becker, et al. (2004) found no correlation between DEHP levels in dust and DEHP urinary metabolite levels in those exposed to the dust.

Response: The comment and reference is noted and will be added for data quality evaluation and integration. Data quality evaluation is an important step in the systematic review process that will be conducted for the draft risk evaluation before integrating sampling data into an evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) stated building materials are a major contributor to the indoor formaldehyde levels and that the highest indoor air levels are associated with mobile homes and homes with urea formaldehyde foam insulation (UFFI). Using TRI and the Homeland Infrastructure Foundation-Level Data (HIFLD) from the Department of Homeland Security, the commenter found that nearly 2,000 mobile home parks within 1 mile of a facility that emitted formaldehyde between the years 2000 and 2018, 5,427 mobile home parks within 3 miles of formaldehyde emitting facilities and 15,808 mobile home parks within 5 miles of formaldehyde emitting facilities.

Response: EPA includes, within this scope, evaluation of consumer exposure to formaldehyde due to off-gassing from building materials not otherwise addressed as part of the risk evaluation. This evaluation will include consumer and bystander exposures (including PESS) to formaldehyde in indoor environments where installation of building materials that off-gas formaldehyde occurs.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0038) recommended evaluation of formaldehyde exposure to consumers in residences and office-workers in commercial buildings under varying environmental conditions, especially higher humidity and/or temperature.

Response: EPA considered this recommendation in finalizing the analysis plan for consumer exposure within residences. EPA is familiar with off-gassing and the potential impacts of temperature (and humidity) on the level of off-gassing of given pollutants. The effects of off-gassing and consumer exposure are also dependent on several other factors including location of the off-gassing product within a residence, whether that area is conditioned or unconditioned, the time of year off-gassing is most prevalent, the surface area from which off-gassing may occur, and other similar factors.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0037) emphasized that neither the scoping document nor the proposed listing document indicate whether EPA will consider tires in the Consumer Use category and sub-category of Toys, Playground and Sporting Equipment as well as Plastic and Rubber Products Not Covered Elsewhere. There are two theoretical exposures to formaldehyde from tires to consumers – exposure due to the consumer directly contacting a new tire and exposure to scrap

tires used as crumb rubber in artificial turf on playing fields and playground surfaces. It was requested that EPA include evaluation of these exposures in the final scope document for formaldehyde.

Response: While tires and tires used as crumb rubber are not specifically called out in the scope document, these materials would be captured within the “rubber products not covered elsewhere” condition of use within the scope document. EPA specifically includes both Toys, Playground and Sporting Equipment, as well as Plastic and Rubber Products within the scope document in Table 2.2 and Figure 2-13 in the draft scope document and carries these sub-categories of conditions of use into the final scope document. Specific pathways and exposure scenarios will be developed during the risk evaluation phase.

Comment: A commenter (EPA-HQ-OPPT-2018-0438-0037) stated that formaldehyde is not a direct ingredient in tire manufacturing, but rather used in the resins, coatings, and tire molds used in the production of tires in small quantities with residual formaldehyde consumed during the curing process. The commenter further emphasized that a vast majority of drivers have their tires installed by retail tire dealers and that regular maintenance, such as checking tire pressure, results in a lifetime exposure that is very low compared to workers.

Response: EPA will utilize reasonably available data identified during its systematic review process and submitted as part of responses to comments when evaluating the potential impact of tires on consumer exposure to formaldehyde. While formaldehyde exposure may be very low compared to workers, if data show consumer exposure to formaldehyde occurs, EPA will need to conduct at least a screening level analysis to consider potential consumer exposures.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0037) stated that EPA’s Crumb Rubber Study, Part 1 findings are consistent with the fact that little formaldehyde remains in tires after use, suggests that little remains after the manufacture of the tire, and that volatile emissions from synthetic turf fields were low.

Response: EPA considered this recommendation during finalization of the scope document.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0038) recommended that the EPA include the assessment of formaldehyde exposure to occupants of buildings where composite panel materials made with urea-formaldehyde adhesives have been used to make furnishings, furniture and cabinets. Including a study on the increased formaldehyde exposure due to higher temperatures and humidity.

Response: EPA is familiar with off-gassing and the potential impacts of temperature (and humidity) on the level of off-gassing of given pollutants. The effects of off-gassing and consumer exposure are also dependent on several other factors including location of the off-gassing product within a residence, whether that area is conditioned or unconditioned, the time of year off-gassing is most prevalent, the surface area from which off-gassing may occur, and other similar factors. A sensitivity analysis of temperature and humidity, as well as other factors, may be included during the risk evaluation phase rather than the scoping phase for formaldehyde.

EPA intends to consider the impact of off-gassing from building products and materials not otherwise addressed to consumers and co-located/co-residence individuals. However, in prioritizing scenarios not addressed by other EPA administered statutes, EPA is excluding a limited group of categorical building products covered by the rule under TSCA Title VI for formaldehyde emission standards for the three

categories of composite wood products and laminated products identified in the scope document). If the materials referenced by the commenter are not captured by the rule under TSCA Title VI and there is evidence of consumer exposure to formaldehyde (which could include urea- and melamine-formaldehyde adhesives as the source) then EPA may conduct at least a screening level analysis to determine the impact of such materials.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) stated that during the production of insulation in which formaldehyde is a component, the curing phase eliminates the free formaldehyde content due to the high temperature and that a vast majority of fiber glass insulation products sold to consumers would have little to no formaldehyde content. The commenter emphasized that these low exposures are further verified with GREENGUARD low-emission certifications.

Response: EPA will utilize data identified during its systematic review process and submitted as part of responses to comments when evaluating the potential impact of formaldehyde off-gassing from insulation products (rigid insulation board, fiber glass, wool products). If reasonably available data show formaldehyde is retained within insulation products, EPA will need to conduct at least a screening level analysis to consider potential consumer exposures as a result of off-gassing.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) stated that historically, the Consumer Product Safety Commission (CPSC) found that emissions from fibrous glass insulation and ceiling tiles would have little impact on in-home formaldehyde levels. The CPSC does not consider the trace amounts of formaldehyde in fiber glass and mineral wool insulation to be of concern to human health or the environment. CPSC relied upon studies conducted by the Oak Ridge National Laboratory.

Response: EPA will utilize data identified during its systematic review process and submitted as part of responses to comments when evaluating the potential impact of formaldehyde off-gassing from building materials like ceiling tiles or insulation products (rigid insulation board, fiber glass, wool products). If reasonably available data show formaldehyde is retained within ceiling tiles or insulation products, EPA will need to conduct at least a screening level analysis to consider potential consumer exposures as a result of off-gassing.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) stated that they rely on GREENGUARD certification to verify their products have low formaldehyde emissions. When GREENGUARD certifies a fiber glass or mineral wool insulation product, it attests that these products meet the California levels found acceptable for schools. Also, products labeled as “formaldehyde free” may still contain trace amounts of the chemical, because manufacturers are permitted to make this claim as long as they do not knowingly add formaldehyde. Products that carry third-party certification, like GREENGUARD Certification, help verify that formaldehyde emission levels are low.

Response: EPA will utilize data identified during its systematic review process and submitted as part of responses to comments when evaluating the potential impact of formaldehyde off-gassing from building materials. If reasonably available data shows formaldehyde is retained within building products evaluated under identified conditions of use, EPA will need to conduct at least a screening level analysis to consider potential consumer exposures as a result of off-gassing.

EPA does not rely on certifications in relation to the degree of impact off-gassing could have on consumer exposure to formaldehyde. Even low levels of off-gassing over a long period of time can lead to longer-term exposures (including chronic exposures).

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) cited a 1991 study from the National Institute for Occupational Safety and Health (NIOSH) of formaldehyde emission levels in a school insulated with fibrous glass. The study concluded that there were low formaldehyde concentrations observed in the classrooms and were within the range of expected non-industrial environments, comparable to ambient levels.

Response: EPA will utilize reasonably available data identified during its systematic review process and submitted as part of responses to comments to inform the development of exposure scenarios falling under the conditions of use to be evaluated in this risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) stated there are documented high indoor air concentrations of formaldehyde, including in many cases far higher than outdoor air levels, and in some extreme cases within the range of occupational level. The same commenter stated EPA must consider the full range of consumer uses when identifying the most exposed subpopulations. In doing so, EPA must consider reasonable scenarios involving multiple consumer uses, such as children and other persons living in mobile homes, where cigarettes, personal care products, and other relevant products are used.

Response: EPA intends to evaluate consumer exposure to formaldehyde resulting from consumer use of formaldehyde-containing products that fall under those consumer conditions of use identified in the scope document. EPA also intends to evaluate consumer exposure to formaldehyde due to consumer personal care products which fall outside of the jurisdiction of other governmental agencies (e.g., FDA).

Comment: Two commenters (EPA-HQ-OPPT-2018-0438-0041, EPA-HQ-OPPT-2018-0438-0047) expressed concerns with use of exposure data that may be outdated from current industry practices. One commenter (EPA-HQ-OPPT-2018-0438-0041) remarked that EPA should “rely only on exposure data collected within a certain time frame (e.g. ≤5yrs) or at minimum set a cut-off date for what constitutes best available monitoring data in the Populations of interest, Exposures, Comparators, and Outcomes (PECO) statement.”

Response: During EPA’s systematic review process, all reasonably available information will be reviewed and evaluated for data quality. The temporal representativeness of data is a factor considered during that data evaluation phase.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0047) stated that EPA should consider oral and dermal exposure to infants and young children to formaldehyde from non-liquid residential products (e.g., carpets, particleboards). The commenter noted that emissions of formaldehyde from these products can occur over extended periods, therefore potential for oral and dermal exposure are possibilities for infants and children.

Response: EPA believes the longer-term exposures the commenter is referring to will be addressed when EPA considers inhalation exposure to consumers and bystanders due to off-gassing from various building and construction products not otherwise addressed. EPA states within the scope document that EPA intends to consider the impact of off-gassing from building products and materials. The effects of off-gassing and consumer exposure are dependent on several factors including temperature, location of the off-gassing product within a residence, whether that area is conditioned or unconditioned, the time of year off-gassing is most prevalent, the surface area from which off-gassing may occur, and other similar factors.

Regarding dermal and oral routes of exposure, EPA does not believe such exposures will be continuous 24 hours per day, 7 days per week like inhalation exposure via off-gassing could be. Additionally, while off-gassing may occur for weeks, months, or years, that is not equivalent to there being a continuous reservoir of formaldehyde for weeks, months, or years through which dermal uptake or oral ingestion would occur to a receptor via periodic contact with the building/construction material.

EPA excludes dermal and oral routes of exposure to bystanders from household products (like a spray cleaner) because upon application to a surface, the high volatility of formaldehyde is expected to cause any residual formaldehyde within the product to rapidly transfer to the gaseous phase which makes it readily available for inhalation uptake (which EPA intends to evaluate), but not for dermal or oral uptake. EPA expects once formaldehyde is in the gaseous phase it will remain in the gaseous phase. As discussed in the draft scope document, formaldehyde is not expected to adsorb to soil/dust within a residence; therefore, dermal or oral exposure to formaldehyde from soil/dust is not expected to occur and therefore would not be available for oral ingestion via ingestion of the soil/dust.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0047) recommended that EPA address whether consumer exposures to formaldehyde from plastics manufactured using formaldehyde-derived polymers will be considered under the scope of the risk evaluation for formaldehyde. The same commenter noted that these exposures are low and considerably lower than exposures from natural sources.

Response: EPA will utilize reasonably available data identified during its systematic review process and submitted as part of the to inform the development of exposure scenarios falling under conditions of use within the scope of this risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0052) noted that the “Draft Scope appears to apply a uniform assumption that building occupants are exposed to any product or material used to construct a particular home or building.” The commenter noted that the draft scope document for formaldehyde identifies a wide range of uses of formaldehyde for building and construction materials and asserts that additional specificity should be added to describe the conditions of use that EPA will consider as part of the risk evaluation. The commenter recommended that EPA consider that consumers (e.g., occupants) may be exposed differently depending on the type of building and construction materials.

Response: EPA describes in the draft scope document that the intention is to evaluate exposure from building and construction materials due to formaldehyde off-gassing from such products/materials. Off-gassing can affect either building occupants or general population, depending on where the product is installed.

Considering the potential exposure situations, EPA will utilize reasonably available data identified during its systematic review process and submitted as part of the comments to inform the development of exposure scenarios falling under conditions of use within the scope of this risk evaluation. These exposure scenarios may include evaluation of different building types and materials as suggested by the commenter depending on the reasonably available data.

Occupational Exposure

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA must account for, and acquire, information needed to accurately evaluate real-world occupational exposures, including personal protective equipment, engineering controls, safety data

sheets, occupational exposure monitoring data, and Permissible Exposure Limits. The commenter stated “EPA must not continue its practice of inaccurately assuming that workers always use personal protective equipment (PPE) or that workplaces are universally compliant with [Occupational Safety and Health Administration] standards” and “the reality that there may be low or no adherence to or effectiveness of such measures.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0040) argued that the “assumed use of a risk management tool in a risk evaluation violates the text and structure of TSCA, in which Congress deliberately separated the risk evaluation and risk management processes” and “is also inconsistent with OSHA regulations.” The commenter also stated that “there is no legal or factual basis for EPA to assume the use of PPE in a TSCA risk evaluation” and that the final scope documents “should made clear that EPA will measure exposure, and determine risk, without regard to PPE use.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0035) recommended that in conducting risk evaluations EPA’s base assumptions should reflect the use of all required PPE.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) stated “Most of EPA’s initial risk evaluations assume the use of Personal Protective Equipment (PPE) in determining whether risks to workers are unreasonable. This approach lacks any legal basis, departs from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to chemicals. As SACC recommended, consistent with the established OSHA hierarchy of controls, EPA should base unreasonable risk determinations for workers on measured or estimated exposure levels in the absence of PPE. If these levels present an unreasonable risk, the necessary measures to protect workers against this risk should be addressed in the subsequent rulemaking under TSCA section 6(a).”

Comment: One commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) stated that EPA needs to consider issues related to occupational use of PPEs in non-factory settings, such as beauty and nail salons citing that beauty salons have far more confirmatory data than any of the other jobs listed in the scope document. The commenter asserted such workers, occupational non-users, consumers, and bystanders, deserve extra scrutiny and protection.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) stated “A persistent area of concern in the first 10 evaluations is EPA’s differentiation between directly exposed workers and the category of ‘occupational non-users’ (ONUs), which EPA generally treats as having lower exposure and risk.” The commenter urged EPA to “replace the broad ONU category with more refined groupings of near- and far-field workers and, within each grouping, conduct a more detailed exposure analysis which reflects job responsibilities and exposure scenarios specific to different types of workers and chemicals.”

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) outlined the following concerns with EPA’s proposed methodology for evaluating occupational exposures and risks: reliance on engineering control and PPE is based on false assumptions; distinction between handlers and ONUs is unsubstantiated and contrary to standard practices; EPA must evaluate oral exposures to all near-field workers; EPA must evaluate dermal exposures to ONUs; and OSHA’s Permissible Exposure Limit (PEL) is outdated and unprotective.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) raised issues related to PPE, asserting that the SACC has repeatedly under-scored, and EPA’s draft evaluations recognize, the expectation of universal PPE use is not grounded in data, departs from established workplace protection policy, and is

contrary to the realities of worker exposure to unsafe chemicals. In each of its reviews of draft evaluations, the SACC has raised concerns about EPA's undue over-reliance on PPE for determinations of unreasonable risk. The commenter stated "EPA is wrong to presume that employers are uniformly implementing PPE or workplace controls sufficient to eliminate unreasonable risks in the absence of any legal obligation to do so. EPA should discard this false and discredited presumption in its all its chemical risk evaluations, including of formaldehyde."

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) asserted EPA did not consider all reasonably available occupational exposure, including existing information that can be readily acquired by EPA. The commenter stated "For instance, the 1,2-diochloroethane risk evaluation references a total of two OSHA workplace sampling events comprising a total of four data points, and impossibly low number for a chemical with an estimated production volume of 20-30 billion pounds per year."

Response: The Agency appreciates this feedback regarding consideration of worker protection practices, such as the use of PPE. EPA's approach for developing exposure assessments for workers is to use the reasonably available information to construct exposure scenarios that are anchored in the real-world use of chemicals. As stated in the scope documents, EPA plans to review potentially relevant data sources on engineering controls (ECs) and PPE to determine their applicability and incorporation into exposure scenarios during risk evaluation. EPA also plans to assess worker exposure pre- and post-implementation of ECs, using reasonably available information on available control technologies and control effectiveness. In addition, EPA plans to analyze exposure to ONUs, workers who do not directly handle the chemical but perform work in an area where the chemical is present. When appropriate, in the risk evaluation, EPA will construct exposure scenarios both with and without PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical. For example, 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 PPE. If the employer determines hazards are present or likely to be present, the employer must mitigate exposures using the hierarchy of controls, which can include selection of the appropriate type(s) of PPE that can protect against the identified hazards. As part of these controls, employers can require employees to use PPE; communicate the selection decisions to each affected employee; and select PPE that properly fits each affected employee. In addition, 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 or not 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 would be described in the risk determination for each condition of use.

EPA generally assumes compliance with OSHA requirements for protection of workers, including the implementation of the hierarchy of controls. In support of this assumption, EPA uses reasonably available information, including public comments, indicating that some employers, particularly in the industrial setting, are providing appropriate engineering or administrative controls or PPE to their employees consistent with OSHA requirements. EPA does not believe that the Agency must presume, in the absence of such information, a lack of compliance with existing regulatory programs and practices. Rather, EPA assumes there is compliance with worker protection standards unless case-specific facts indicate otherwise, and therefore existing OSHA regulations for worker protection and hazard communication will result in use of appropriate PPE in a manner that achieves the stated Assigned Protection Factor or Protection Factor. EPA believes this is a reasonable and appropriate approach that accounts for reasonably available information and professional judgment related to worker

protection practices, and addresses uncertainties regarding availability and use of PPE. EPA will examine the reasonably available information to determine what type of data gaps exist and how those gaps impact further analysis. This effort will be informed by data evaluation efforts that will aid in the determination of data needs that will be used to exercise TSCA data gathering authorities.

In regard to ONUs, these are defined in this document as workers who do not directly handle the chemical but perform work in an area where the chemical is present. Where information is reasonably available, EPA may provide a more granular analysis of exposure by specific work activities. While EPA typically assumes ONUs perform work in the far-field when modeling exposure, EPA may model specific work activity pattern on a case-by-case basis.

In regard to oral exposure, as discussed in the scope document, the frequency and significance of oral exposure are dependent on several factors and are difficult to predict. EPA will consider oral exposure on a case-by-case basis.

In regard to dermal exposure, EPA does not currently plan to evaluate dermal exposure to ONUs. If during the TSCA systematic review process data is found that indicates ONUs may be exposed via the dermal route, then EPA will consider this on a case by case basis.

In regard to the OSHA PEL, EPA acknowledges that certain PELs may be outdated. EPA considers actual exposure levels at workplaces when performing risk evaluation.

In regard to the specific reference to consideration beauty and nail salons in the context of the use of PPE in non-factory settings, EPA notes that TSCA excludes cosmetics from the statutory definition of “chemical substance,” so chemical use in beauty and nail salons may fall outside TSCA jurisdiction. Similar issues are addressed in discussions in the “Non-TSCA Uses” section of this document.

In regard to 1,2-dichloroethane, the scope document presents data and information that EPA plans to consider during risk evaluation. In developing TSCA risk evaluations, EPA will consult with inter- and intra-agency partners and will review all reasonably available information, including additional workplace sampling data obtained through systematic review or other sources.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0033) expressed concern that EPA might rely on existing OSHA PELs for individual chemicals as the basis for determining whether workplace chemical exposures are excessive and thus represent unreasonable risks of adverse health effects. The commenter stated that the current OSHA PELs are out-of-date and inadequately protective. The commenter expressed particular concern about six chemicals for which the OSHA PELs are substantially higher, and therefore substantially less protective, than the corresponding exposure limits promulgated by the NIOSH, the American Conference of Governmental Industrial Hygienists (ACGIH) and the California Occupational Safety and Health Administration (CalOSHA), specifically *o*-dichlorobenzene, *p*-dichlorobenzene, 1,2-dichloroethane, ethylene dibromide, formaldehyde, and phthalic anhydride.

The commenter urged EPA to disregard those specific PELs when evaluating the levels of risk associated with routine workplace exposures to these six chemicals and expressed concern that EPA will fail to recognize that despite legally-mandated workplace exposure limits, workplace overexposures do occur, even if the various OSHA PELs were adequately protective. The commenter also recommended

that reviews of the NIOSH, ACGIH, and CalOSHA exposure limits be included in the scope of each Risk Evaluation along with their respective supporting documents.

The commenter stated that the frequency and magnitude of workplace overexposures can be appreciated by review and evaluation of the OSHA's Data and Statistics, which includes inspection information, industrial hygiene air sampling data, and severe injury reports, among other data. The commenter also stated that during the anticipated duration of an individual's work life, there is a significant likelihood that the worker will experience cumulative exposures that exceed the respective health-based values promulgated to protect the general population. The commenter urged EPA to explicitly consider the cumulative exposures of exposed workers in light of these cumulative exposure guidelines for the general population.

Response: EPA does not rely on the OSHA PEL for a chemical to make an unreasonable risk determination. EPA uses actual monitoring data of worker exposures and/or modeling approaches to estimate occupational exposures. EPA may consider the influence of OSHA PEL to characterize exposure estimates and in certain modeling approaches (such as EPA/OPPT's OSHA Particulates Not Otherwise Regulated PEL-limiting model), but EPA acknowledges that workers may experience exposure above the OSHA PEL. EPA then integrates the information from the exposure assessment and hazard assessment to characterize risk for each condition of use.

EPA acknowledges that workers, consumers and the general population may be exposed via the inhalation, dermal and oral routes and that these exposures may be additive across routes, pathways, receptors and chemical stressors. Exposure scenarios will be developed based on the reasonably available information, weight of the scientific evidence and best available science approaches.

Comment: A commenter (EPA-HQ-OPPT-2018-0421-0027) cautioned EPA on appropriateness of OSHA inspection and NIOSH Health Hazard Evaluation (HHE) data, stating "It is unclear how or if the EPA will incorporate these data sources into the risk evaluation. Before doing so, EPA should carefully consider the quality and representativeness of these data. First, the OSHA Inspections and NIOSH HHEs are a result of workplace complaints or suspected hazards, and therefore, are unlikely to represent typical workplace conditions with respect to potential exposures and health and safety industrial practices. Use of these data in the risk evaluation, either for a specific condition of use or in condition of use bridging, may overestimate realistic workplace exposures."

Response: During risk evaluation, EPA plans to consult OSHA and NIOSH to obtain data and information that may be reasonably available in addition to the online databases. EPA acknowledges that OSHA inspection data may not represent typical workplace exposures and will carefully consider any uncertainty and data needs in the reasonably available data. All exposure data and information will be evaluated for quality prior to integrating into the risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) asserted that EPA has no plan for measuring exposures by ONUs. The commenter claimed that "Supervisors have very different exposure patterns than skilled trade workers and janitorial workers; the latter group may have some of the highest exposures of all workers" and that "EPA's assumptions about ONU exposures wholly unsupported." The commenter also noted "In the draft scopes, EPA assumes that ONUs will have no dermal exposures, an assumption that is unfounded for many cleaning workers and skilled trade workers. Particularly over a short period (e.g., response to a spill or equipment maintenance), ONU exposures may be as great as or greater than those of other workers, and many ONUs are even less likely to be provided PPE. In

modeling inhalation exposures, EPA assumes ONUs are only present in the ‘far-field’ zone—outside of the ‘near-field’ workers’ zone. However, ONUs may not stay within the “far-field” zone when they are responding to spills, maintaining equipment, and otherwise performing work activities that take them within the “near-field” zone occupied by direct users.” The commenter recommended “For the coming risk evaluations, EPA should abandon its overbroad ONU category and instead make separate, data-driven risk determinations for the various types of workers that are exposed to the risk evaluation chemicals without directly handling the chemicals themselves.”

Response: ONUs are likely a heterogeneous population of workers, and some could be exposed in the near-field zone. EPA includes ONUs within the scope of data collection activities for all 20 High-Priority Substances. These data collection activities include searching exposure information from peer-reviewed literature, gray literature, information submitted to the Agency under TSCA sections 4, 5, 8, and FYI submissions. EPA will review all reasonably available data and information on potentially exposed employees (including ONUs) for the specific chemical and condition of use to determine the best approach to estimate exposures and develop fit-for-purpose exposure assessments. This may include using measured air concentration data and/or exposure modeling. EPA will consider variations in work activities and ONU exposure levels for each exposure scenario.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) stated that EPA’s methodology of dividing occupations into whether the worker’s job description includes direct contact with the chemical is a false dichotomy, and inconsistent with the state of the science for industrial exposure assessment. The commenter further emphasized that among experts of occupational exposure assessment, there is no such thing as EPA’s ONU and that the term “ONU” or “occupational non-user” does not appear on a search of PubMed – the NIH medical library of over 10,000 scientific journals – or on a “google” search, other than in EPA TSCA documents. Rather, EPA should use the appropriate designations for near- and far-field workers, with the appropriate assigned exposure and should assess all near-field workers as having exposure to formaldehyde as appropriate. Additionally, EPA should do a much broader outreach to get all the information that is “reasonably available” – as required by TSCA and should include TURI staff, union health and safety staff, industrial hygienists, and government experts at the local, regional, and state level as appropriate. The same commenter stated that EPA’s erroneous presumption that ONUs will not directly handle formaldehyde stems from EPA’s misapplication of near-field and far-field exposure models. The commenter further states by mis-classifying all ONUs as far-field, EPA is failing to address the near-field exposures that ONUs experience as workers are subjected to numerous exposures. EPA confirms that it intends to overlook the potential for dermal exposures to ONUs for liquid contact during numerous activities (Draft Scope, Appendix F, p. 115-133). This commenter emphasized EPA’s failure to fully assess all routes of exposure for near-field workers that will leave many workers – including men and women of reproductive age and other vulnerable populations – in harm’s way and violates TSCA.

Response: ONUs are likely a heterogeneous population of workers, and some could be exposed in the near-field zone. EPA includes ONUs within the scope of data collection activities for all twenty chemicals. EPA will review all reasonably available data and information on ONU for the specific chemical and condition of use to determine the best approach to estimate exposures. EPA will consider variations in ONU exposure levels for each exposure scenario.

In regard to the suggestion to conduct broader outreach to obtain reasonably available information, such issues are discussed in the “Information Considered and Additional Data-Gathering” section of this document.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) stated that the OSHA formaldehyde PEL is outdated, indefensible, and unprotective. The commenter stated that it fails to meet the best available science requirement of Section 26 of TSCA and urged EPA to assess occupational risks using the most updated scientific evaluations including NIOSH and limits of 0.016 ppm 8-hr TWA.

Response: EPA will review and analyze all reasonably available information to estimate occupational exposures and risk.

Comment: One commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) stated that EPA must evaluate oral exposures to all near-field works, instead of a case-by-case basis stated in the draft scope document. The commenter stated that EPA failed to include the oral route of exposure for either workers or ONUs in its modeling for either liquid or vapor exposures. Oral exposures should be included in every evaluation – failing to do so may underestimate exposures significantly.

Response: As described in the draft scope documents, EPA will evaluate oral exposure on a case-by-case basis, considering all reasonably available data and information. EPA will develop exposure scenarios and will then determine if the oral route is an applicable route of exposure. An assessment of the oral route will depend on the chemical physical and chemical properties (e.g., vapor pressure), as well as on the exposure scenario (e.g., if a condition of use will generate a mist).

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0040) asserted that the draft scope documents “overlook reasonably available data on occupational exposures.”

Response: EPA considers the review of reasonably available exposure monitoring data for specific condition(s) of use as the first step of the analysis plan for occupational exposure. This step follows the data collections efforts that EPA deems necessary to gather all reasonably available information for the specific chemical and conditions of use. EPA will consider the use of surrogates and/or ESDs/GSDs only if data needs remain after all reasonably available information has been collected and reviewed.

EPA consults regularly with its federal partners (e.g., OSHA, NIOSH) and will consult with state agencies if they have relevant occupational exposure data. Additionally, EPA plans to continue consulting with OSHA and NIOSH during development of the risk evaluation. Regarding monitoring data from other sources, EPA provides several opportunities for all entities to submit workplace monitoring data or other information for consideration in the risk evaluation. This information will be evaluated through data evaluation criteria to ensure the highest quality data is used for risk assessment purposes.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) asserted that the draft scopes fail to consider known exposure pathways, specifically identifying chemical mists for conditions of use that involve the spray application of a chemical as an example. The commenter noted that “mists can be generated from non-aerosol uses as well, such as include the use of ‘operational fluids,’ ‘hydraulic fluids,’ and other liquids uses for which EPA expresses no plans to consider mist exposures.” The commenter recommends that EPA “must either evaluate mist exposures or provide evidence that mist generation is not known, intended, or reasonably foreseen” and “[e]ven ‘low’ inhalation exposures, however, can cause or contribute to unreasonable risk, particularly when combined with other exposure pathways.”

Response: In Appendix E of the draft scope documents, EPA provides process information based on preliminary data gathering. EPA made initial determinations of potential mist exposures based on these process descriptions. EPA will ultimately consider the potential of mist exposure for a condition of use based on review of all reasonably available information. EPA welcomes additional information from the commenter that may be applicable including specific examples of the operations where mist is generated. During any operations involving spray application, EPA believes it is reasonable to expect mist exposure to workers, therefore, this pathway was included in the initial conceptual model for all chemicals where spray application is expected.

EPA considered preliminary data and expert judgment to develop the conceptual model, including potential exposure routes. Based on EPA's experience in conducting exposure assessments, fugitive emissions of chemicals with very low vapor pressures under ambient conditions are often below the limit of detection, such that the associated inhalation exposures are negligible. During risk evaluation, EPA includes reasonably available data and information in its assessment, including information on inhalation exposures. In addition, EPA will consider reasonably available data and information and use the best available science to determine whether to consider aggregate exposure for a particular chemical.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) supported EPA's evaluation of occupational exposures to polymers made from 1,3-butadiene monomer used in tire manufacturing. The same commenter encouraged EPA to use actual data provided by representative industry members to assess occupational exposures to 1,3-butadiene for both workers and occupational non-users.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) agreed with EPA's finding that residual 1,3-butadiene in rubber products, including tires, is expected to be low and therefore occupational exposures are also expected to be low. The commenter mentioned that throughout the various processes involved in tire manufacturing, PPE and local ventilation may be present to reduce the exposure potential for materials used in tire manufacturing, but not used to reduce exposure explicitly to 1,3-butadiene (i.e., to reduce the exposure potential for other tire materials). The commenter stated "because the amount of 1,3-butadiene in synthetic rubber compounds is so low, tire manufacturers do not utilize any specific PPE or engineering controls specifically for 1,3-butadiene."

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) recommended that the dermal exposure pathway for tire manufacturing workers be removed from the draft scope because "[i]n tire manufacturing, the synthetic polymers used to manufacture tires may contain very low residual amounts of 1,3-butadiene (less than 50 ppb), however, the synthetic polymers are received as solid bales and are not in a liquid form. As such there is no potential for worker dermal exposures to liquids containing 1,3-butadiene in tire manufacturing."

Response: EPA appreciates feedback from potentially affected entities and will consider this information during development of the draft risk evaluation for 1,3-butadiene, as relevant and appropriate. EPA does not plan to evaluate dermal exposure for commercial uses of tires by workers and occupational non-users as illustrated in Appendix F.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) agreed with EPA that oral exposures to 1,3-butadiene are not present in tire manufacturing facilities because "[t]he nature of the tire manufacturing work functions does not result in oral exposure . . . [and] the primary source of 1,3-BD is from bales, not liquid. As with dermal exposure, many standard personal protective requirements

minimize or prevent incidental oral exposure.” The commenter recommended that this exposure pathway be removed from the evaluation for tire manufacturing workers.

Response: EPA appreciates feedback from potentially affected entities and will consider this information during development of the draft risk evaluation for 1,3-butadiene, as relevant and appropriate.

Comment: A commenter (EPA-HQ-OPPT-2018-0433-0031) stated that occupational exposures are minimal during the manufacturing and handling of DEHP, and all appropriate PPE is employed to minimize any exposures during operations, transfers, and preparations for shipping.

Response: Thank you for the comment, EPA will consider this information during the preparation of the risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0504-0043) asserted that, in regard to dicyclohexyl phthalate, the category “Repackaging” should not include a liquid contact scenario evaluation. The commenter stated “The only way this scenario could occur is if the substance were being handled as a molten material; as noted in Appendix B, the melting point of the substance is 66°C. We believe this to be an unlikely repackaging situation. Also, EPA uses the 2016 CDR data (‘manufacture in solid form’) as rationale in the Manufacturing life cycle stage to remove liquid/dermal contact to workers from evaluation plans (page 66), so the logic should follow to the Repackaging life cycle stage.”

Response: The intent of the repackaging scenario, in addition to the repackaging of pure materials, is to capture the possibility of the repackaging of formulations containing dicyclohexyl phthalate which may be liquid formulations.

Comment: A commenter (EPA-HQ-OPPT-2018-0476-0028) recommended that firefighters be included for occupational exposure, as well as a susceptible subpopulation, in regard to TCEP. The same commenter (EPA-HQ-OPPT-2018-0462-0033) recommended that EPA thoroughly research populations who live or spend significant time in institutional settings, such as dormitories, and their exposures to TBBPA for susceptible subpopulation identification. The commenter also suggested that the same logic be extended to other similar spaces, such as group homes, assisted living homes, hotels, and prisons.

Response: In past risk evaluations (e.g., HBCD), data on dust concentrations in residential and occupational microenvironments have been extracted and integrated into general population and occupational (background) assessments. These included data on chemical concentrations found in indoor dust from schools, dormitories and other areas, provided that the data was reasonably available in the literature and had acceptable data evaluation scores. For the TCEP risk evaluation, EPA will investigate exposure to firefighters.

Comment: Two commenters (EPA-HQ-OPPT-2018-0446-0034, EPA-HQ-OPPT-2018-0428-0029) emphasized the necessity of critically evaluating generic scenarios, ESDs, and models for their appropriate use in this risk assessment. The commenter stated that these tools “may be acceptable to provide the EPA with an initial exposure estimate, but they should not take the place of evaluating empirical data. Similarly, the older sources listed in Table 2-6. Potential Sources of Occupational Exposure Data are not substitutes for evaluating empirical data. There are several additional sections within the Draft Scope where the EPA should critically review models to apply them as necessary and warranted.” The commenter urged EPA to use only high-quality data sources for information regarding potential exposures to chemicals. The EPA should ensure that it provides strong justification for each

model used as the foundation for a risk determination and must not make decisions that go beyond the ability of the models.

Response: The commenter correctly stated that OECD ESDs present standard approaches for estimating occupational exposures and environmental releases, when more specific information on the chemical or use process is not reasonably available. As part of the risk evaluation process, EPA may identify additional data through systematic review and will evaluate all reasonably available data and information. When integrating occupational exposure and environmental release data/information for risk evaluations, EPA normally uses the highest rated quality data from TSCA systematic review among the higher level of the hierarchy of preferences.

Comment: A commenter (EPA-HQ-OPPT-2018-0438-0041) remarked that the “continued step of polycondensation, whether starting from the formaldehyde and urea monomers or utilizing the methylol syrup with additional urea, would better describe the most prevalent UF and MF industrial resin synthesis.” The commenter suggested “EPA should describe the polycondensation of these resins in the final scoping document.”

Response: In Appendix E of the draft scope documents, EPA provides process information based on preliminary data gathering. EPA has included a sentence that polycondensation is the prevalent synthesis pathway based on this feedback from industry.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0041) urged EPA to consider the “conservative risk assessment that served as the foundation for the health protective OSHA standard” and that the scope of the risk evaluation for formaldehyde document “should also include some specific discussion in the final scoping document that references 29 C.F.R. §1910.1048.”

Response: The OSHA standard for formaldehyde is discussed in Section 2.3.5 Occupational Exposures, which provides a brief discussion of the requirements of the standard. EPA does plan to consider the relevant information in the risk assessment that served as the foundation of the OSHA standard and its requirements during the risk evaluation as part of the systematic review process. EPA believes the scope document adequately addresses the occupational exposures that EPA plans to evaluate and applicable occupational exposure limits.

Comment: A commenter (EPA-HQ-OPPT-2018-0438-0054) supported EPA’s evaluation of occupational exposure to materials manufactured with formaldehyde used in tire manufacturing.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) provided compiled industrial hygiene data for tire manufacturing processes for formaldehyde exposure. The commenter encouraged use of “actual data provided by [the commenter’s] members to assess occupational exposures for both workers and occupational non-users.” The commenter also noted “personal protective equipment (PPE) and local ventilation may be present to reduce the exposure potential for materials used in tire manufacturing.”

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) agreed with EPA that oral exposures to formaldehyde are not present in tire manufacturing facilities.

Response: EPA appreciates feedback from potentially affected entities and will consider this information during development of the draft risk evaluation for formaldehyde, as relevant and appropriate.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) emphasized that EPA’s prioritization process recognizes that formaldehyde exposures in the fiber glass and rock and slag wool insulation industry is already thoroughly regulated, has documented low exposures, and poses no unreasonable risk. This commenter requests that EPA determine formaldehyde to be a Low-Priority Substance and if during the risk assessment process it is found to be a High-Priority Substance, that EPA decides that the use of formaldehyde in fiber glass and mineral wool insulation production does not present an unreasonable risk and should not be subject to further regulation.

Response: EPA has already designated formaldehyde as a High-Priority Substance and has initiated a risk evaluation on this substance. Through the risk evaluation process, EPA will determine if formaldehyde presents an unreasonable risk under its conditions of use. EPA will conduct the risk evaluation in accordance with statutory and regulatory requirements applicable to the performance of TSCA risk evaluations.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) acknowledged that EPA has determined that the current formaldehyde air emissions from both fiber glass and mineral wool manufacturing processes pose an acceptable risk under the Clean Air Act. The employee exposure levels within the manufacturing plants are similarly regulated by OSHA and these limits are established with a PEL. The commenter emphasizes the stringent emission limits for products established by the State of California which are certified by GREENGUARD and other organizations.

Response: Ambient air releases of formaldehyde from industrial and commercial stationary sources are covered under the jurisdiction of other EPA statutes (specifically the CAA and RCRA) as described in Section 2.6.3. This can be seen in Section 2.6.3.1, 2.6.3.2, and Figure 2.16 in the draft scope document. Formaldehyde is a listed hazardous air pollutant under Section 112 of the Clean Air Act. EPA will consider the OSHA standard for formaldehyde as part of a review of all reasonably available information to assess occupational exposures.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) encouraged EPA to reconsider the use of OSHA Chemical Exposure Health Data (CEHD) and NIOSH HHE program data because the data are outdated. The commenter stated “although the EPA has limited the exposure data from OSHA’s CEHD to be within the last 10 years, the data were collected as part of compliance inspections and may not be representative of typical employee exposures. OSHA acknowledges that their compliance officers have limited time to conduct an inspection and cannot completely characterize all exposures for all employees and based on their professional judgment often attempt to evaluate worse case chemical exposure scenarios.”

Response: EPA will review all reasonably available data, which includes information from NIOSH and OSHA. The quality of these data will be evaluated as part of the Agency’s systematic review process. These data will be evaluated per the process and metrics presented in the [Application of Systematic Review in TSCA Risk Evaluations](#)

For Table Appendix E-2, EPA provided all OSHA inspection monitoring data identified in the CEHD from 2010 to 2019 by North American Industry Classification System (NAICS) code. However, some of the OSHA inspection monitoring data may not be applicable based on the scope of this risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0038) recommended EPA assess formaldehyde exposure to workers and consumers for “composite panel materials made with urea-formaldehyde adhesives . . . used to make furnishings, furniture and cabinets” and provided a reference for a study on

influence of “higher temperatures and humidity” (Frihart, C. R., J. M. Wescott, and T. L. Chaffee 2020. Long-Term Formaldehyde Emissions Potential from Urea-Formaldehyde – (UF-) and No-Added Formaldehyde- (NAF-) Bonded Particleboard). The commenter emphasized that “workers handling composite wood products in any form including flat panels, especially under conditions of increased temperature and/or humidity” need to be considered.

Response: With the exception of those panels excluded from the scope of the risk evaluation, EPA will assess worker exposure during processing and use of composite panel materials made with urea-formaldehyde adhesives. EPA will consider the influence of environmental factors as necessary based on the review of the reasonably available information.

EPA is familiar with off-gassing and the potential impacts of temperature (and humidity) on the level of off-gassing of given pollutants. The effects of off-gassing and consumer exposure are also dependent on several other factors including location of the off-gassing product within a residence, whether that area is conditioned or unconditioned, the time of year off-gassing is most prevalent, the surface area from which off-gassing may occur, and other similar factors. A sensitivity analysis of temperature and humidity, as well as other factors, may be included during the risk evaluation phase rather than the scoping phase for formaldehyde.

EPA intends to consider the impact of off-gassing from building products and materials not otherwise addressed to consumers and co-located/co-residence individuals. However, in prioritizing scenarios not addressed by other EPA administered statutes, EPA is excluding a limited group of categorical building products covered by the TSCA Title VI for formaldehyde emission standards for the three categories of composite wood products identified in the scope document. EPA will consider the study referenced in the comment in our reviews of the reasonably available information, which is subject to a data quality evaluation under EPA’s systematic review process.

Comment: One commenter (EPA-HQ-OPPT-2018-0459-0035) raised concerns related to the Agency’s evaluation of workplace exposure to phthalic anhydride, stating that it “will be based on information that is not reflective of current industry practice.” The commenter encouraged EPA to “seek sources of recent exposure data to conduct its risk characterization for phthalate anhydride. If necessary, we urge the Agency to consider the [threshold limit values] in any modeling of occupational exposures.”

Comment: One commenter (EPA-HQ-OPPT-2018-0428-0029) mentioned that “member companies are interested in sharing information with EPA regarding procedures, engineering controls, and PPE which minimize worker exposure. The [commenter] recommends that the EPA tailors its focus on worker activities based on these real world practices.”

Response: EPA appreciates the comments and welcomes additional data and information.

Comment: One commenter (EPA-HQ-OPPT-2018-0428-0029) noted the “ATSDR Toxicological Profile relies upon references to occupational exposures in the Japanese printing industry. These occupational exposures are significantly different than the [commenter’s] members’, who use PDC as a chemical intermediate in a closed system. In fact, printing is not included in Table 2-2. Categories and Subcategories of Conditions of Use included in the Scope of the Risk Evaluation. Overall, the EPA’s review of the ATSDR Toxicological Profile is a good starting point; it contains a comprehensive summary of the information available for PDC. However, the [commenter] submitted comments on a number of inconsistencies in presentation of the information and in derivation of the minimum risk

levels (MRLs) that require correction and would like the Agency to consider these comments while performing the risk evaluation.”

Response: EPA reviews all reasonably available information in performing TSCA risk evaluations. Table 2-6 provides several examples, among many potential sources of occupational exposure data, that EPA plans to consider during the risk evaluation process. EPA appreciates the comments and will carefully consider all data and information, including any inconsistencies among the data sources.

Comment: One commenter (EPA-HQ-OPPT-2018-0444-0028) stated concern that the “Agency’s evaluation of workplace exposure to o-DCB will be based on information that is not reflective of current industry practice. The Scope lists three sources of occupational exposure data that generally include data that are more than a decade old and that may reflect agency investigations of violations or alleged violations. The draft references OSHA’s regulatory limit of 50 parts per million (ppm) as a exposure ceiling limit, but does not indicate that the American Conference of Governmental Industrial Hygienists (ACGIH) has established a threshold limit value (TLV) of 25 ppm as an 8-hour time weighted average (TWA). Although ACGIH values are not mandatory, many companies elect to comply with TLVs – particularly when a TWA permissible exposure limit (PEL) has not been established by OSHA. We encourage EPA to seek sources of recent exposure data to conduct its risk characterization for o-DCB. If necessary, we urge the Agency to use the TLVs in any modeling of full-shift occupational exposures.”

Response: During risk evaluation, EPA plans to consult OSHA and NIOSH to obtain data and information that may be reasonably available in addition to the other sources (e.g., peer-reviewed literature). EPA acknowledges that OSHA inspection data may not represent typical workplace exposures and will carefully consider any uncertainty and data needs in the available data. EPA welcomes recent occupational exposure data and this information will be evaluated for quality prior to integrating into the risk evaluation. The final scope of o-dichlorobenzene includes reference to the ACGIH threshold limit value.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040), in regard to TBBPA, asserted that the draft scope documents lacked specificity related to workers’ oral exposure. The commenter stated that EPA possessed the “authority, and obligation, to generate and collect data for use in TSCA risk evaluations, as opposed to merely evaluating those routes for which EPA is already in possession of relevant data.”

Response: The oral exposure statement is a standard statement used for all scope documents supporting TSCA risk evaluations and will not be updated. In regard to use of Agency information collection authority, such issues are addressed in discussions in the “Information Considered and Additional Data Gathering” section.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0038) recommended that the terms “furnishings” be expanded to include furniture and cabinets since these represent products used for many years and providing the longest time-period of potential exposure to formaldehyde.

Response: The information in the life cycle diagram is grouped according to the CDR processing codes and use categories. The product category descriptions can be found in EPA’s Instructions for Reporting 2016 TSCA Chemical Data Reporting. Furnishings refer to chemical substances contained in furniture and furnishings made from metal, wood, leather, plastic or other materials that are intended for consumer or commercial use should be reported under this code. Examples of products include movable

and installed furniture such as tables, chairs, benches, desks, cabinets, shelving, stools, television stands, display cases, bookcases, and storage units. This code does not include foam seating and bedding products.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0038) recommended that EPA add exposure analysis of workers handling composite wood products including flat panels, especially under conditions of increased temperature and/or humidity to the scope of the risk evaluation for formaldehyde.

Response: EPA will analyze exposures to workers handling finished composite wood products with the exception of three types of composite wood products (hardwood plywood, particleboard, and medium density fiberboard [including thin-medium density fiberboard]) in panel form and as component parts and finished goods, which are currently regulated under the Formaldehyde Emission Standards for Composite Wood Products final rule (see 40 CFR 770) and are not included in the scope of this evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0051) emphasized that asphalt roofing manufacturing, asphalt processing, and fiberglass mat production are different processes with different potential for exposure to formaldehyde. The commenter stated that referenced information provided by the commenter was confusing and misleading and provided clarification for its usage in the draft scope document.

Response: EPA appreciates the feedback, the reference on p.103 was for the use of formaldehyde containing resins incorporated into articles. EPA reviewed the information provided on asphalt processing by the commenter, and based on the process description for asphalt processing, formaldehyde appears to be generated as a byproduct due to oxidation in blowing still and is not a component of asphalt coating. Under such circumstances, formaldehyde generated as a byproduct of asphalt processing is outside the scope of this risk evaluation. EPA believes that its regulatory tools under TSCA section 6(a) are better suited to addressing any unreasonable risks that might arise from formaldehyde as a byproduct through regulation of the activities that generate formaldehyde as a byproduct or cause it to be present as a contaminant than addressing them through direct regulation of formaldehyde.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0047) expressed concern with the use of EPA generic scenarios and OECD Emission Scenario Documents as some “are more than 5 years old . . . [and] some are as many as 26 years old.” The commenter encouraged EPA to use more recent empirical data when possible.

Response: EPA would appreciate the submission of empirical data. Through our systematic review process, the Agency will collect and review all reasonably available data identified through our data gathering steps described in Section 2.1. These include such reasonably available information as EPA generic scenarios and OECD Emission Scenario Documents. During the data evaluation process, EPA will consider temporal representativeness of the data as a factor in the quality of such data. The exposure assessment will be based on the reasonably available information, weight of the scientific evidence and best available science approaches.

Comment: A commenter (EPA-HQ-OPPT-2018-0438-0050) submitted usage data on formaldehyde use as a reducing agent and recommended the conceptual model be updated to characterize the exposure potential.

Response: EPA appreciates the process information. EPA agrees with the commenter and revised the conditions of use table and corresponding exposure mapping table for the copper plating process for a better reflection of the life cycle stage and type of processing of formaldehyde.

Environmental Exposure

Comment: One commenter (EPA-HQ-OPPT-2018-0446-0034) in regard to Table 2-4 of the p-dichlorobenzene draft scope document, asserted that the amount of water releases of p-dichlorobenzene (< 5 lbs) do not represent a significant release to surface water. They also asserted that there is no need for the EPA to evaluate environmental effects from releases during plastics manufacturing and recommends it be excluded from the Final Scope. They state that “p-DCB has been shown to be biodegradable, and not bioaccumulative, and thus is not a Persistent Bioaccumulative Toxic . . . chemical. Therefore, the EPA does not need to conduct a PBT assessment of p-DCB and recommends it be excluded from the Final Scope.”

Comment: A commenter (EPA-HQ-OPPT-2018-0444-0028) noted that the draft scope document “suggests that EPA will evaluate environmental releases and exposures of o-DCB as part of its analysis, including an assessment of impacts on ground and surface water and the persistent, bioaccumulation, and toxic . . . potential of the substance. The draft also notes, however, that releases to water totaled a mere 7 pounds from the seventeen facilities reporting environmental release to [TRI] for 2018. Consequently, the manufacture and use of o-DCB does not result in significant releases to surface water and an investigation of releases/exposures in surface water need not be included in the risk evaluation.”

*Response: TRI data is only one source of surface water release data. EPA will also examine the loadings calculated through DMR and data collected through systematic review. In the prioritization designation and draft scope documents, EPA presented data showing high bioconcentration in fish (measured BCF ≤ 1800 in *Poecilia reticulata*; ECHA, 2019). In the prioritization documents and draft scope documents, EPA presented data showing low bioconcentration in fish (measured values in fish ≤ 560 ; Oliver and Niimi, 1983) but high bioconcentration in other species (measured BCF = 6,212–19,700 in the algae *Selenastrum capricornutum*; Casserly et al., 1983). The results of systematic literature review will be integrated during risk evaluation to assess the overall bioconcentration and bioaccumulation potential of p-dichlorobenzene and o-dichlorobenzene.*

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0053) provided process information on the use of formaldehyde in semiconductor industry and noted that the amount used is below TRI reporting threshold.

Response: EPA will review other data sources as part of the review of all reasonably available information, including TRI data. EPA welcomes information specific to formaldehyde use in semiconductor manufacturing that the commenter provided with this submission.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) offered several comments on exposure via water (i.e., drinking water, groundwater, surface water) and associated biota for 1,3-butadiene:

1. Exposure and risks to aquatic and terrestrial organisms have been evaluated previously by authoritative sources and have been found to be negligible.
2. Exposure to man via drinking water and consumption of environmental receptors are considered to be negligible, compared to exposure via ambient air for 1,3-butadiene.

3. Weight of evidence suggests that 1,3-butadiene is rapidly degraded both abiotically as well as biotically in aquatic systems.

The same commenter agreed with EPA's determination to not evaluate general population exposure from inhalation of ambient air because potential health risk from this pathway is adequately managed under the Clean Air Act and to not evaluate general population exposure from oral, dermal or inhalation exposures associated with drinking water because potential risks from these pathways are adequately managed under the Safe Water Drinking Act.

Response: In regard to item 1, negligible amounts of 1,3-butadiene as reported in other evaluations are of importance to the upcoming 1,3-butadiene evaluation. This information helps to provide a thorough picture of the distribution of 1,3-butadiene in the environment. Thus, low levels of 1,3-butadiene in aquatic and terrestrial organisms will be considered in EPA's assessment of 1,3-butadiene.

As to items 2 and 3, EPA continues to evaluate reasonably available data concerning presence and concentrations of 1,3-butadiene in the environment (including in water, fish, or terrestrial organisms). In aerobic aquatic environments, 1,3-butadiene was not observed to be readily biodegradable as it achieved only 0–4 percent degradation over a 28-day incubation period using a sludge inoculum and the OECD 301C, Ministry of International Trade and Industry (MITI) test method. Based on these results, this chemical may persist in subsurface environments, groundwater, or enclosed pipes when volatilization is not an option. This is regardless of how low or high the concentrations of 1,3-butadiene are. EPA has considered all reasonably available data concerning 1,3-butadiene concentration and will consider additional data and information as it becomes reasonably available.

Exposure to the general population from 1,3-butadiene in drinking water is under the jurisdiction of the SDWA and is not in the scope of the risk evaluation for 1,3-butadiene. As explained in more detail in Section 2.6.3 of the final scope documents, 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 1,3-butadiene using authorities in TSCA sections 6(b) and 9(b)(1).

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) noted that existing drinking water data demonstrates little exposure to formaldehyde and that water releases of formaldehyde are not expected from tire manufacturing. The commenter also stated that member tire manufacturing facilities follow best practices to reduce the risk of chemical releases. In their comment they noted a 2016 study done by EPA Region 10 and the Washington State Department of Ecology that conducted water sampling and field analysis at 10 federal and state fish hatcheries in Washington and in Idaho to provide data on the concentrations of formaldehyde being discharged from hatcheries after applications of formalin (i.e., a solution of 37% formaldehyde gas dissolved in water), which was used by the hatcheries to control external parasites on hatchery fish and their eggs. The commenter stated that the study concluded that formalin use at hatcheries covered by the National Pollutant Discharge Elimination System General

Permit is not likely to affect salmonids listed under the Endangered Species Act (ESA) in concentrations below 10 ppm formaldehyde in the receiving water.

Response: EPA considered the information provided as to evaluate final pathways to include in the scope document for formaldehyde. EPA also considered monitoring data associated with formaldehyde in water, identified through EPA's systematic review process, to develop final pathways to be evaluated for environmental exposures. All sources of data and information, including those from industry, are carefully evaluated and integrated according to EPA's systematic review methods when considering possible sources of industrial releases of formaldehyde, which are not limited to tire manufacturing. The water pathways within the scope are ambient and groundwater pathways.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) asserted that EPA need not evaluate the impact of formaldehyde on biosolids or sediments considering: (1) formaldehyde is a highly volatile gas and expected to partition predominantly to the atmosphere; (2) that formaldehyde is not expected to adsorb significantly to soil or sediment or bioconcentrate in fish or aquatic organisms; and (3) in order to accumulate in biosolids, formaldehyde will need to be discharged in a significant quantity, not volatilize as it is transported from point of generation in a tire manufacturing plant or from tires in use into the sewer system. The commenter also noted that biosolids can only accumulate formaldehyde if they have adhered to soil particles and notes the ATSDR Toxicological Profile for Formaldehyde states formaldehyde is not expected to attach easily to solids.

Response: EPA plans to utilize data identified during its systematic review process and submitted as part of responses to comments when evaluating the potential impact of biosolids and associated releases of formaldehyde from biosolids for environmental exposure. EPA acknowledges the low soil adsorption potential and bioaccumulation in fish in Section 2.7.2.2 of the scope document. While formaldehyde may have low soil adsorption potential, biosolids may contain some water within which may contain formaldehyde. Therefore, if data shows formaldehyde is retained within biosolids as applied to land, EPA will need to conduct at least a screening level analysis to consider potential environmental exposures.

Human Hazard

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA must identify and evaluate cancer hazard and risk wherever one or more authoritative bodies have identified cancer potential. Specifically, the commenter pointed to the following statement in the scope documents: "If cancer hazard is determined to be applicable to [SCOPE CHEMICAL], EPA plans to evaluate information on genotoxicity and the mode of action for all cancer endpoints to determine the appropriate approach for quantitative cancer assessment in accordance with the U.S. EPA Guidelines for Carcinogen Risk Assessment (U.S. EPA, 2005)," and asserted "This statement suggests that EPA is questioning whether there is a cancer hazard for any of these chemicals. Yet for 12 of the 20 high-priority chemicals, EPA already identified cancer as a hazard category in its earlier prioritization dossiers. Moreover, for these 12 chemicals, one or more authoritative bodies have already indicated there is evidence for cancer hazards."

Response: EPA is not ignoring authoritative evidence from previous hazard assessments for carcinogenesis. In fact, this was one of the key determinants for why 12 of the 20 High-Priority Substances were prioritized on the original TSCA Work Plan in 2012 and again in 2014. The text stating EPA will evaluate information on genotoxicity and mode of action is part and parcel of systematic

review of the literature and part of the data evaluation process that will be undertaken during risk evaluation.

Comment: Another commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) noted that none of the analysis plans for the 20 chemicals indicate whether EPA will use the unvetted policy of selecting the most “representative” study(ies) instead of the study(ies) with the most sensitive human health endpoint for hazard characterization and noted “EPA employed this ‘representative study’ concept for the first time in the draft trichloroethylene (TCE) risk evaluation.” The commenter also stated “The factors for selecting a ‘representative’ health endpoint do not include sensitivity and appear to be arbitrary and capricious, designed to provide the agency with complete discretion to ignore the most sensitive endpoint” and “there is no scientific justification for this new policy, which is at odds with longstanding agency-wide risk assessment practices.” The commenter recommended that EPA not use this representative policy for any chemical risk evaluations conducted under TSCA or any other statute.

Response: *The use of representative studies for selecting adverse outcome domains has been a widely accepted practice for some time in both cancer and noncancer hazard assessment. Representativeness in TSCA risk evaluations goes beyond picking that study with the lowest point of departure. It also includes evaluation of data quality, sensitivity of the endpoint, and weight of the scientific evidence, which has multiple criteria. Representative health endpoints are not chosen arbitrarily but based upon Bradford-Hill considerations which help describe the robustness of the selection considerations rather than just picking the lowest number to derive a health protective endpoint. The TSCA approach relies on development of a range of endpoints for utilization in the characterization of potential hazard(s) and risk(s) related to different conditions of use. Stakeholders can agree or disagree with selection of endpoints that describe the hazard that are used for dose-response; however, the Agency will continue to provide justification and documentation of its choices through its systematic review process.*

Comment: A commenter (EPA-HQ-OPPT-2018-0504-0038) stated that DEHP has a wide range of effects, including DNA modification in male and female gametes, potentially causing delayed puberty and other reproductive health effects in offspring of exposed animals. DEHP also can cause metabolic disorders or obesity through a variety of mechanisms such as changes in metabolism and glucose homeostasis, epigenetic inheritance or direct promotion of adipogenesis. Numerous studies show effects by DEHP on the female reproductive system including interference with steroidogenesis and effects on uterine structure and function. High-dose DEHP studies in animals showed potential for adverse birth outcomes. DEHP can also disrupt thyroid hormone biology at low doses.

Response: *Section 2.4.2 of the final scope document for di-ethylhexyl phthalate states that EPA plans to evaluate the reasonably available evidence for several broad health effects categories, including developmental and reproductive effects. Effects on gametes that impact subsequent health outcomes fit into the broad categories of reproductive and developmental effects. While EPA did not identify metabolic effects of di-ethylhexyl phthalate during prioritization, these effects may be identified through the systematic review process. EPA is currently in the process of reviewing the quality of studies identified through the systematic review process. Once all information is evaluated and integrated, EPA may include additional health endpoints in the evaluation. EPA will consider the information collected through the systematic review process to characterize the weight of evidence and dose-response for specific endpoints.*

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0038) noted that BBP inhibits testosterone production and has effects on sexual differentiation in male animals and mammary gland growth in female animals.

Response: The final scope document for butyl benzyl phthalate states that EPA will evaluate broad human categories, including reproductive, developmental and systemic toxicity. Hormone regulation and sexual differentiation fall within the broad categories of reproductive and developmental effects. EPA is currently in the process of reviewing the quality of studies identified through the systematic review process. Once all information is evaluated and integrated, EPA will consider the information collected through the systematic review process to characterize the weight of evidence and dose-response for specific reproductive and developmental endpoints.

Comment: A commenter (EPA-HQ-OPPT-2018-0504-0038) noted that DBP is estrogenic and anti-androgenic and has been associated with increased fetal weight and epigenetic transgenerational inheritance of adult-onset obesity in animal models. DBP has effects on the female and male reproductive system; some of these include alterations in pubertal timing and alterations in mammary gland development. DBP also has potential effects on thyroid hormone levels and dose- and age-dependent effects on neuroendocrine systems.

Response: EPA plans to evaluate a range of broad hazard effect categories, including developmental, reproductive, and systemic effects. Effects of dibutyl phthalate on reproductive hormones, fetal weights, adult-onset obesity following developmental exposures, effects on the male and female reproductive systems (including pubertal timing and mammary gland development), and thyroid effects on the neuroendocrine system would all fit under the broad categories the EPA plans to evaluate. EPA is currently in the process of reviewing the quality of studies identified through the systematic review process. Once all information is evaluated and integrated, EPA may identify additional health endpoints to include in the evaluation. EPA will consider the information collected through the systematic review process to characterize the weight of evidence and dose-response for specific endpoints.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0034, EPA-HQ-OPPT-2019-0131-0045), in regard to Dicyclohexyl phthalate and Di-isobutyl phthalate, references toxicity reviews by the U.S. Consumer Product Safety Commission: “In the case of Dicyclohexyl, the review found that exposure induced changes in animal body weight, liver weight and reproduction and development. Likewise, exposure to Diisobutyl phthalate was found to induce changes in body weight, and liver, kidney and thyroid weight. Sufficient animal data also existed to support the conclusion that the chemical was a reproductive and developmental toxicant. Specifically, Di-isobutyl phthalate induced reproductive effects and developmental effects were reported in both male and female reproductive systems and tissues.”

Response: The final scope documents for both di-isobutyl phthalate and dicyclohexyl phthalate state that EPA will evaluate evidence for broad health effect categories including reproductive, developmental, and systemic toxicity. The specific health endpoints described by the commenter fall within the broad health effect categories described in the scope. EPA is currently in the process of reviewing the quality of studies identified through the systematic review process. Once all information is evaluated and integrated, EPA may identify additional health endpoints to include in the evaluation. EPA will consider the information collected through the systematic review process to characterize the weight of evidence and dose-response for specific endpoints.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0040) stated “In reviewing the gray literature available for consideration in the systematic review, EPA failed to identify an assessment of EDC conducted by the Texas Commission on Environmental Quality (TCEQ). This resource may provide additional insight outside of the resources already identified by EPA on EDC hazard and dose response. Importantly, the TCEQ assessment includes the derivation of a cancer inhalation unit risk that reflects literature not available when EPA last assessed EDC under the IRIS program in 1987. There are significant other references that EPA must consider when considering hazards for EDC. [The commenter’s] science consultant, Cardno ChemRisk has prepared the information in Appendix A included in this letter to provide a more comprehensive review of available contemporary information on hazards associated with EDC. EPA should include this in its revised scoping document.”

Comment: A commenter (EPA-HQ-OPPT-2018-0421-0026) asserted “For risk characterization, EPA should use health protective defaults and methods that generate risk estimates.”

Response: Systematic review is not completed. As described in the scope documents, EPA has initiated the process of searching for, collecting, and screening the data and information for the scopes of the next 20 High-Priority Substances, and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase, not scoping. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions. The information provided will be considered during the risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0038) was concerned that EPA has already selected a subset of human health hazards for further evaluation without describing the process used to arrive at this decision. The commenter stated “For instance, EPA has selected reproductive and developmental effects and cancer as hazards for DEHP, but DEHP has also been reported to cause metabolic disorders and effects on thyroid hormone biology.” During the prioritization process, the commenter had submitted a list of effects for several phthalates based on information in the Endocrine Society’s Second Scientific Statement on endocrine-disrupting chemicals, this information is included in the appendix to this letter. The commenter then asked EPA to more fully describe the process by which hazards were included or excluded for each chemical under review. In the actual risk assessment, hazard evaluation should bear more consideration than exposure since exposures can change through time due to unexpected uses, changes throughout the product life cycle and new uses.

Response: EPA has devoted significant resources to its search and screening of all literature as illustrated in the literature trees of the draft scope documents. EPA provides more information in final scope documents in interactive literature trees following title abstract and full text screening and hazard tables/heat maps, which show relevant hazard data and information to be evaluated and integrated during the risk evaluation. For the risk evaluation, EPA will apply the data quality criteria described in [Application of Systematic Review in TSCA Risk Evaluations](#) to evaluate all studies identified through full text screening. EPA will then extract data from studies of acceptable quality for inclusion in hazard characterization, evidence integration, and dose-response analysis.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) urged EPA to treat any increased cancer risk to workers exceeding 1×10^{-6} as unreasonable, thereby triggering risk management under TSCA section 6 and to use this benchmark to determine whether cancer risks to workers and consumers are

unreasonable under TSCA. The commenter stated “TSCA, by contrast, is anchored in the concept of ‘unreasonable risk’ (a term that implies a lower risk threshold than the OSH Act concept of ‘significant risk’). No provision of TSCA provides that workers should receive less protection than other exposed subpopulations or that well-established EPA benchmarks for unacceptable cancer risks would be inapplicable to workers. Indeed, workers are specifically identified as a ‘potentially exposed or susceptible subpopulation’ that EPA is required to protect in section 3(12) of TSCA, indicating that Congress was particularly concerned by the levels of toxic chemicals in the workplace and the special vulnerability of some employee populations to their adverse health effects.”

Response: Currently, EPA calculates cancer risk and arrays benchmarks against risk ranges for consideration in making unreasonable risk determinations. Benchmarks are not bright lines, but guideposts to decision making in unreasonable risk determinations.

TSCA section 3(12) lists examples of human receptors that may be considered PESS but provides for EPA to identify the relevant subpopulations for each chemical substance. Workers are one example of human receptors that may be identified as PESS in individual chemical risk evaluations.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0048) asserted that EPA should not revisit definitive findings in IRIS assessments unless there are new data that inform its evaluation of the weight of the evidence. The commenter stated “EPA should modify IRIS findings only where there is a strong justification, such as the availability of new data that inform the weight of the scientific evidence. Such additional data should be reviewed by the TSCA program, in consultation with IRIS scientists, to assess whether they might inform the determination of the weight of the evidence for the relevant endpoints. This review should be conducted using a peer-reviewed systematic review methodology as described above, not the TSCA systematic review method. Where the TSCA program concludes that a new weight of evidence determination is warranted based on new data or other considerations, the draft evaluation should explain why EPA is revisiting previous IRIS conclusions.”

Response: EPA considers previous assessments, hazard identification, and dose-response analysis. The Agency also considers weight of evidence analysis done in previous assessments. However, under TSCA, EPA considers all reasonably available information. Therefore, EPA will apply systematic review evaluation criteria as presented in the [Application of Systematic Review in TSCA Risk Evaluations](#) to all literature/studies, including IRIS assessments. The two programs are actively collaborating on systematic review approaches.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0052) expressed concern about the use of phthalates in plastics, stating that they endanger public health and the environment. The commenter stated that marine species from plankton to invertebrates to large pelagic fishes have been shown to ingest microplastics (or prey that contain them) (Romeo et al. 2015) and thus people who ingest aquatic plants or seafood may be exposed to dangerous levels of contaminants. The commenter continued “Robust medical evidence links various persistent organic pollutants commonly found on microplastics with a host of human illnesses, including cancers (e.g., breast cancer, pancreatic cancer, non-Hodgkin’s lymphoma, adult-onset leukemia, and soft tissue sarcomas), neurological disorders (e.g., attention deficit disorder, impaired memory, learning disabilities, and behavioral problems), and reproductive disorders (e.g., menstrual disorders, abnormal sperm, miscarriages, pre-term delivery, low birth weight, altered sex ratios, and shortened lactation periods) (CIEL 2019a). Many of these persistent organic pollutants bioaccumulate and biomagnify up the food chain, posing a risk of harm for higher trophic-level organisms, including humans (Wasserman et al. 1979; Gobas et al. 1995; Rochman et al. 2013).”

The commenter also provided information on the discovery that microplastic is contaminating drinking water supplies: “Scientists have only recently studied plastic pollution in freshwater, but it is now documented in groundwater (Panno et al. 2019), and it is at least as ubiquitous in rivers and streams as it is in marine environments (Koelmans et al. 2019; McCormick et al. 2016). For example, a scientist recently swam the length of the Tennessee River—the drinking water source for 4.7 million people—and found one of the highest concentrations of microplastics in the world (Tennessee Aquarium 2018). Samples showed 18,000 particles per cubic meter of water, which is 8,000 percent higher than measurements in the Rhine and 80 percent higher than measurements in the Yangtze River—the source of 55 percent of all river-born microplastic entering the ocean (*Id.*)” The commenter urged EPA to “ensure a robust evaluation of downstream exposure from consumer use and disposal of plastics made using phthalates.”

Response: The commenter’s concerns about the life cycle for plastics and its environmental impacts are duly noted. It does not appear that the commenter has identified new data of the health impacts of phthalates in plastics for humans or other ecological receptors. The current approach the Agency is focused on in the Office of Water is to promote the reduction of microplastics and trash to limit multipollutant exposure. Based on reasonably available information for exposure and hazard in aquatic environments, it is presently not feasible to assess the risk for disposal of plastic products as a COU.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) asserted that EPA should address chronic health risks to consumers, stating that “Routinely, the initial 10 evaluations have only addressed acute exposure scenarios for consumers and disregarded evidence of repeated exposure and chronic health risks. As we have explained in our comments, this approach is flawed.” The commenter asserted that EPA: (1) did not consider indoor air concentrations of [first 10 chemicals] (some at extremely high levels), which indicate that consumer exposure is not episodic but continuous; (2) failed to consider the likelihood of chronic exposure from consumption of contaminated drinking water and long-term environmental exposure from the presence of chemicals in ambient air and at waste sites; and (3) assumed one-time or very intermittent product use. The commenter mentioned that, while EPA’s draft assumes use of a single product type during a day, many consumers likely use different products containing these chemicals on the same day or over time, even apart from other evidence that consumers have chronic exposure, intensive users of consumer products are plainly exposed to the chemicals on a recurring basis.

Response: EPA considers the physical and chemical properties, fate and transport properties and conditions of use when determining relevance of the exposure scenarios and health outcomes that are most appropriately considered for the condition of use and exposure scenario. For asbestos, chemical characteristics and carcinogenic hazards both informed the acute and chronic exposures scenario and risk estimation. For many of the other first 10 chemicals subject to risk evaluation, the half-life of the chemicals is hours or days. The use patterns identified for the conditions of use were assessed to be short-term, acute and subacute, in some instances, for many consumer products. Aggregating exposure across conditions of use is an important subject that the SACC underscored, and of the first ten evaluations, EPA did address aggregate exposure in in the draft risk evaluation for HBCD based on reasonably available information and the weight of the scientific evidence regarding the conditions of use, physical and chemical properties, fate and transport properties, and exposures.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0034, EPA-HQ-OPPT-2018-0434-0037, EPA-HQ-OPPT-2018-0501-0041, EPA-HQ-OPPT-2018-0503-0032, EPA-HQ-OPPT-2018-0504-0041) stated “Ortho-phthalate esters . . . are a harmful class of chemicals largely used as plasticizers in a

variety of products—both subject to TSCA and not—including consumer products such as toys, household cleaning products, personal care products, modelling clay, insecticides, leather products, and food packaging. Because phthalates are not structurally bound to products, they can ‘easily leach out and be ingested, inhaled, dermally absorbed, or can directly enter the bloodstream.’ These factors contribute to the fact that coexposure to multiple phthalates is ubiquitous in the United States. Further, exposure to phthalates has been associated with toxicities ranging from male reproductive malformations to neurodevelopmental effects.”

Response: EPA appreciates this feedback regarding the risk evaluation process and will take it into account in the subsequent stages of the risk evaluation process.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0041) noted that understanding the role of endogenous formaldehyde is critical to determining potential health risks from exogenous exposures which would meaningfully alter normal homeostatic control of metabolically generated formaldehyde. EPA failed to mention in the draft scope an assessment of endogenous vs. exogenous exposure in the risk evaluation. In the final scoping document, EPA should update its Analysis Plan to clearly include an evaluation of endogenous exposure and its role/impact on determining human health risk.

Response: EPA will review the reasonably available information and will evaluate endogenous and background exposures during the risk evaluation phase.

Comment: One commenter (EPA-HQ-OPPT-2019-00131-0048) emphasized that EPA should immediately release the draft IRIS assessment for public comments and submit it to the NAS for peer review. If TSCA scientists have concerns about the scientific basis for IRIS findings, they should be framed for public comments and reflected in the charge for NAS review. EPA’s risk evaluation should then respond to NAS recommendations and explain and justify any departures from the draft IRIS assessment.

Response: EPA used the existing IRIS assessment mentioned above to include these chemicals in the 2012 workplan, and this information factored into High-Priority Substance designation. EPA will be using information developed from draft IRIS hazard and dose response assessment in the TSCA Risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) stated that EPA must consider susceptibility factors as part of the risk evaluation as described in the IRIS assessment which reported that evidence from studies of occupational or residential formaldehyde exposures “support an association with deficits in pulmonary function among adults and children,” noting that respiratory symptoms also were reported at the same exposure levels.

Response: EPA acknowledges that populations living in close proximity to identified sources of emissions from manufacturing, processing use or disposal may experience greater exposure than the general population. In reviewing the reasonably available exposure information, EPA considers the spatial and temporal relevance of the information in building each exposure scenario for the identified conditions of use.

In determining the exposure estimates associated with the identified COU, EPA incorporates variability and uncertainty into its estimates, presenting a central tendency and high-end estimate and includes a range of intake values, activity patterns and other values for the expected routes of exposure, to account

for differences across populations. EPA also considers relevant life stages for estimated exposures and incorporates exposure factors appropriate to the age and behavior.

EPA plans to consider biological susceptibility in its evaluation of exposure and human health hazard. EPA has not yet completed the data evaluation and evidence integration steps of the systematic review process and is reviewing the reasonably available human health hazard information to identify the appropriate hazards and susceptibilities associated with each High-Priority Substance. EPA is aware of the concern for asthmatics and other with pulmonary disease as a PESS.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0035) stated that EPA fails to reference the stalled IRIS assessment, despite previously stating that the recent formaldehyde IRIS assessment will inform the process. Furthermore, EPA must immediately release the recently updated IRIS assessment for public comment and NASEM review so that the Office of Pollution Prevention and Toxics (OPPT) can directly utilize the extensive work already done by NASEM and EPA IRIS scientists. The commenter also cited a 2019 report from the Government Accountability Office which raised concerns about potential political interference through EPA leadership's leading to an unexplained directive to halt the formaldehyde assessment.

Response: EPA used the existing IRIS assessment mentioned above to identify formaldehyde as a workplan chemical in 2012 and this information factored into High-Priority Substance designation. EPA will be using information developed from draft IRIS hazard and dose response assessment in the TSCA Risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049) encouraged EPA to utilize the scientific information that may be available from completed federal, state and international agency chemical assessments and ensure that those assessments withstand the scientific rigor required by TSCA. EPA must ensure that there is consistent application of the TSCA systematic review and data integration approach for any information relied upon in the risk evaluation, including any information that is drawn from the IRIS program.

Response: In response to SACC and public comments received during the first 10 chemical risk evaluations and the [Application of Systematic Review in TSCA Risk Evaluations](#), as well as in response to the prioritization and draft scope documents, EPA plans to publish the "Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances." This protocol document outlines in detail the current systematic review process EPA is utilizing for the next 20 chemical risk evaluations. EPA will be providing the public with an opportunity to comment on this document.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049) stated "To the extent that EPA is able to refine the focus of hazard endpoints of concern based on searches performed during the prioritization phase or on other assessments identified during the scoping phase, this information should be included to inform stakeholders."

Response: EPA has enhanced the presentation of information about the hazard endpoints in the final scopes. Information identified as a result of the screening process used for prioritization and then systematic review are identified in Section 2.4 and in the new heat maps for environmental and human health hazard in Section 2.1.

Environmental Hazard

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) asserted “None of the 20 scoping documents confirm whether or not adequate data exist on the impact of these chemicals on wildlife, even when the chemical is known to bioaccumulate in fish or where monitoring data exist, documenting its presence in air, ground and/or surface water, sediment, or soil.” The commenter also claimed that “No ecological targets are identified, though both aquatic and terrestrial organisms are acknowledged as possible targets,” and suggested that “If data are truly lacking, this is the time for the agency’s enhanced testing authority to be exercised.”

Response: The information provided in the scope documents includes information presented in the Proposed Designation documents, as well as information identified through title and abstract and full text screening of references using systematic review methods. Data quality evaluation is an integral step in the systematic review process that will be conducted for the draft risk evaluation to identify relevant environmental hazard data to characterize and establish environmental hazard thresholds. Although there may be data regarding environmental fate and exposure, there may not be environmental toxicity data for the same exposure pathways and organisms. Fate, exposure and environmental hazard studies evaluated through systematic review are evaluated independently and integrated, if relevant, for use in the risk characterization. EPA is currently in the process of identifying data needs that may be filled by implementing testing authorities under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA considers data submitted through public comment as well as through secondary supplemental searches and welcomes the submission of additional data. Any data or information received during the scoping or risk evaluation processes will be considered.

Information Considered and Additional Data Gathering

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) cited 15 U.S.C. § 2625(k) and 40 CFR.702.33 to describe EPA’s requirement to consider “reasonably available” information in conducting risk evaluations of High-Priority Substances, including “information that EPA possesses or can reasonably generate, obtain and synthesize for use, considering the deadlines specified in 15 U.S.C. 2605(b) for prioritization and risk evaluation.” The commenter called on EPA to use its authorities under TSCA sections 4 and 8 to obtain additional information (“EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps” and “[a]ny information that EPA can obtain through the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is ‘reasonably available information’”). The commenter also stated that “EPA should not rely on data on surrogate or analog chemicals as a substitute for obtaining data directly on the chemicals undergoing risk evaluation” and that [r]elying on voluntary requests for information will result in limited, biased, inaccurate, or incomplete information on the chemicals.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA cannot ignore a release of or exposure to a chemical on the basis that it cannot attribute it to a particular condition of use and stated that “EPA must conduct risk evaluations under TSCA that consider all ‘reasonably available’ information relating to a chemical substance, including information that may not be tied to specific conditions of use.” The commenter argued that such data are still relevant to determining whether the chemical substance presents an unreasonable risk, and as such must be considered by EPA.

Comment: One commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) noted the inability to evaluate emissions data for a significant number of chemicals due to the absence of TRI

data and asserted that EPA must fill these data gaps, and obtain/publish the emissions data for these chemicals, and then include the resulting exposures in its risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0427-0040) urged EPA to consider additional information, including: gathering information from industry regarding similar exposure groups to represent occupational exposure potential more accurately during chemical manufacturing; incorporating an understanding of frequency with which non-routine tasks with higher potential for exposure occur to determine an average daily exposure estimate for use in risk characterization.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0035) raised concerns regarding the use of the Agency's TRI and CDR programs, as well as public comment and recommended data sources to identify the conditions of use in all 20 draft scope documents. The commenter stated "[t]his broad-brush approach used by EPA for the second and third set of scope documents appears to be the same as the approach used for the first ten TSCA high priority chemicals." Another commenter (EPA-HQ-OPPT-2018-0434-0037, EPA-HQ-OPPT-2018-0501-0041, EPA-HQ-OPPT-2018-0504-0041, EPA-HQ-OPPT-2018-0430-0027, EPA-HQ-OPPT-2018-0458-0028, EPA-HQ-OPPT-2018-0476-0027) recommended that EPA seek out reasonably available information beyond CDR and TRI reporting and pointed to the fact that six of the twenty high-priority chemicals (DIBP, DCHP, TCEP, TPP, HHCB, BBP) are not reportable under TRI and the 25,000-pound manufacturing/importing reporting threshold for CDR. In addition to adding certain High-Priority Substances to TRI and requiring reporting below the CDR threshold for those chemicals, the commenter suggested that the Agency seek information from its own Superfund program and state counterparts, as well as affirmatively request that federal, state and local governmental bodies provide information about the High-Priority Substances during the scoping phase.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) expressed concern that "EPA may rely heavily on unwarranted, conservative assumptions when evaluating uses relevant to paints, coatings, sealants and adhesives, since exposure information specific to these products may not be readily available." The commenter acknowledged EPA's "willingness to accept information from industry, to minimize such assumptions . . . [but] has not identified and requested necessary information during the scoping phase or early in the risk evaluation process." The commenter requested that EPA analyze data gaps and specific assumptions used in lieu of other, possibly more accurate data. publish detailed, voluntary requests for information, specific to each condition of use and identify test methods where relevant.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0047) described how previous TSCA section 8(d) rules had sunsetted during the 1990s: "p-dichlorobenzene; o-dichlorobenzene; 1,2-dichloropropane; dibutyl phthalate (DBP) (1,2-benzene- dicarboxylic acid, 1,2- dibutyl ester); di-ethylhexyl phthalate (DEHP) - (1,2-benzene- dicarboxylic acid, 1,2- bis(2-ethylhexyl) ester); di-isobutyl phthalate (DIBP) - (1,2-benzene- dicarboxylic acid, 1,2- bis(2-methylpropyl) ester); dicyclohexyl phthalate; and phosphoric acid, triphenyl ester (TPP) sunsetted in 1992. *See* 40 C.F.R. § 716.120. The reporting periods of prior § 8(d) rules for butyl benzyl phthalate (BBP) - 1,2-benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester and tris(2-chloroethyl) phosphate (TCEP) sunsetted in 1993. *Id.* The reporting period of the prior § 8(d) rule for 4,4'-(1-methylethylidene)bis[2, 6-dibromophenol] (TBBPA) reporting period sunsetted in 1995. *Id.* The reporting period of the prior § 8(d) rule for 1,2-dichloroethane; 1,1,2-trichloroethane; and 1,1-dichloroethane sunsetted in 1997. *Id.*" The commenter urged EPA issue new TSCA section 8(d) rules "[g]iven scientific advancement over the last two decades . . . calling in health and safety studies would likely provide EPA with additional valuable information to assess the hazards, exposures, and risks posed by these chemicals." The commenter also stated "EPA has never issued § 8(d) rules for

trans-1,2- dichloroethylene; ethylene dibromide; 1,3-butadiene; 1,3,4,6,7,8-hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB); formaldehyde; and phthalic anhydride. *See* 40 C.F.R. § 716.120. Thus, issuing § 8(d) rules for those chemicals is even more important.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) noted EPA use of industry-generated studies that were conducted outside the United States under the European Union Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), including European Chemicals Agency (ECHA) studies. The commenter stated “These summaries are prepared by industry and are considerably less detailed than actual study reports. Thus, before relying on the summaries to support a finding of no unreasonable risk, EPA must obtain and independently evaluate the underlying studies. In addition, EPA must adopt a uniform policy of treating REACH-generated studies and data provided for use in a risk evaluation as ‘health and safety studies submitted under [TSCA]’ and therefore subject to section 14(b)(2)(A), which expressly prohibits EPA from withholding such studies as confidential business information This will assure the public a meaningful opportunity to comment on the scientific basis for EPA’s proposed determinations of risk.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0047) requested that EPA require the submission and generation of environmental and health hazard and exposure data where they are currently lacking and stated “[t]o ensure transparency, EPA must accurately describe the information it relies on and must obtain and make public full health and safety studies. The commenter also asserted that EPA continues to mischaracterize data it cites as sourced from ECHA, that it is not clear whether EPA has or intends to obtain access to the full studies in the ECHA dossiers, and that EPA must obtain and make public health and safety studies.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) emphasized the importance of conducting risk evaluations to a high degree of accuracy and developing conclusions of high confidence to develop effective risk mitigation strategies that are specifically tailored to a condition of use. The commenter offered that “Industry input and participation in this process would assist EPA in identifying accurate evaluation methods and data. To that end, while recognizing EPA’s openness and commitment to public engagement at all stages of the risk evaluation process, [the commenter] notes that the process would be enhanced by early and specific identification of data gaps, assumptions and data that could result in risk evaluation conclusions of low confidence. Early identification of data needs followed by specific and clear, voluntary requests for data would increase the quality of EPA’s data sets and its final risk determinations.” The commenter also stated concerns that “EPA may base risk evaluations on conservative assumptions that are not representative of most or even all products considered within a condition of use. Because of the complexity of data required to accurately evaluate complex formulations over several varying product types, [the commenter] requests EPA provide details about reasonably available information for each condition of use it plans to evaluate, as well as provide an opportunity for public comment.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) requested that EPA further engage industry by providing information about data sources and data gaps as early in the scoping or risk evaluation process as possible with an opportunity to comment. The same commenter requested “While matching data sources to conditions of use during scoping, . . . EPA analyze data gaps and specific assumptions used in lieu of other, possibly more accurate data . . . [and] that EPA publish detailed, voluntary requests for information, specific to each condition of use, and identify test methods.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0034, EPA-HQ-OPPT-2019-0131-0045) recommends that the agency contact state environmental offices and EPA regional offices to gather data on the environmental harms that can be caused by improper disposal of chemicals, including TBBPA, HHCB, BBP, dicyclohexyl phthalate, and di-isobutyl phthalate.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0048) urged EPA to identify data-gaps on the 20 High-Priority Substances and require testing under TSCA section 4 to fill such gaps.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) stated “The SACC has been highly critical of the adequacy of the information EPA has used to assess exposure in the initial 10 evaluations and called for EPA to ‘obtain better data and documentation’ from industry ‘on conditions of use, exposures, and potential for worker exposures.’ However, the 20 scopes do not indicate that EPA will take any additional steps to obtain use and exposure data that are not available in public sources. For all the 20 high-priority chemicals, EPA should immediately put in place a comprehensive process for obtaining information and data from industry, backstopped by TSCA information collection authorities.”

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0022) recommended EPA seek out reasonably available information beyond CDR and TRI reporting.

Comment: One commenter (EPA-HQ-OPPT-2018-0458-0033) suggested that EPA consider screening and risk assessments of Phosphoric acid, triphenyl ester performed by other countries and their regulatory bodies as it considers the final scope of the risk evaluation.

Response: In developing the draft scope documents, EPA leveraged the data and information sources already described in the document supporting the High-Priority Substance designations. EPA conducted a comprehensive search to identify and screen multiple evidence streams (i.e., chemistry, fate, release and engineering, exposure, hazard), and the results of which to date are provided in each scope document. EPA considered additional information, as appropriate, identified following publication of the draft scope document, including data received via public comments, in developing the final scope documents. EPA also welcomes additional information related to the risk evaluation process.

EPA is using the systematic review process described in the [Application of Systematic Review in TSCA Risk Evaluations](#) document to guide the process of searching for and screening reasonably available information, including information already in EPA’s possession, for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation. For the next 20 High-Priority Substances’ scope documents, EPA has completed and presents searches of publicly available literature and the title and abstract and full-text screening of the resultant studies. EPA will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies’ key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions.

As part of the risk evaluation process for each of the High-Priority Substances, EPA will continue to consider additional reasonably available information and will evaluate it during development of the draft risk evaluation. For any data needs identified through the process, EPA may use the Agency’s

TSCA authorities under sections 4, 8 or 11, as appropriate. For example, data needs for occupational monitoring and other information have been identified for various chemical substances undergoing risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0462-0038) urged EPA to consider the current state of the science for TBBPA and use the most relevant research available in its risk evaluation for TBBPA and provided a list of studies, including those published by Environment Canada and Health Canada and the American Chemistry Council.

Response: EPA considers reasonably available information and uses the best available science to evaluate existing chemicals under TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act. EPA thanks the commenter for providing these references, as all studies submitted via public comment will be considered for the draft risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0050) noted that reacted phthalic anhydride cannot leach from an alkyl polymer into the environment.

Response: EPA plans to investigate this issue further in the risk evaluation on whether these types of products contain residual amounts of phthalic anhydride or its hydrolysis product versus reaction products made from phthalic anhydride. In addition, EPA is reviewing data associated with leaching or emission rates from products. EPA considers data submitted through public comment as well as through secondary supplemental searches and welcomes the submission of additional data should the commenter have additional information.

Comment: One comment (EPA-HQ-OPPT-2018-0428-0030), in regard to 1,2-dichloropropane, stated “when querying the scoping documents, only 8 of 15 mention IRIS . . . meaning EPA’s Draft Scoping documents fail to cite an IRIS assessment for almost half of the high priority chemicals which have completed assessments. “

Response: EPA is conducting gray literature full-text screening and is including among the cited sources the IRIS document in the final scope for all High-Priority Substances.

Comment: One comment (EPA-HQ-OPPT-2019-0131-0047) urged EPA to complete the IRIS program human health hazard assessment of formaldehyde and that EPA “should rely on this assessment in the risk evaluation of formaldehyde.”

Response: EPA plans to use information developed from draft IRIS hazard and dose response assessment in the TSCA risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0041) implored EPA to inform stakeholders early on if the Agency plans to designate a time point at which it will no longer consider newly developed or published scientific information.

Response: EPA appreciates this feedback regarding the risk evaluation process.

Systematic Review

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026) asserted that EPA’s TSCA systematic review methodology “continues to have serious scientific flaws and is inconsistent with established,

validated methods. This flawed methodology lacks transparency and is not empirically based, making it likely to result in biased evaluations of the evidence for these 20 chemical substances.” The commenter recommends that EPA should incorporate the following comments and recommendations made by EPA’s SACC that are relevant to flaws we have identified in the systematic review process for these 20 chemical substances:

- ***The EPA SACC in its Peer Review of PV29 commented:*** “The Committee discussed the need to publish peer reviewed pre-established protocols for each of the Agency’s reviews prior to performing the actual risk assessment. The protocol for PV29 was created concurrently with the review, which is contrary to best practices for systematic reviews”
- ***The EPA SACC in its Peer Review of 1,4 Dioxane commented:*** “Committee members did not find the systematic review to be a transparent and objective method for gathering the relevant scientific information, scoring its quality, and integrating the information evaluate.”
- ***The EPA SACC in its Peer Review of 1-BP commented:*** “The Committee generally concluded that it was difficult at best to determine exactly what was done during the SR . . . Committee members expressed that they experienced challenges in trying to follow the actions taken in the SR, and how the results of the SR were used in the draft risk assessment.”
- ***The EPA SACC Peer Review of 1-BP commented:*** “Several Committee members discussed in depth that it was not appropriate to determine an “unacceptable” rating during data quality evaluation based solely on one criterion.”
- ***The EPA SACC Peer Review of 1,4 Dioxane recommended:*** “Do not be overly stringent and exclude studies based on a single criterion.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) discussed that, while the draft scope documents indicate that searching and screening have already been completed for gray literature, publicly available databases of peer-reviewed literature, and TSCA submissions and such “documentation is helpful, it is only a small portion of the information that should be available for BD using the processes indicated in the Draft Scope.” The commenter stated that “[a]s a result of the limited reporting in the Draft Scope, meaningful comments cannot be provided regarding the approach, identification, or selection of evidence for the risk evaluation.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) stated “[t]o be in alignment with systematic review methods, the public would have had an opportunity to comment on the approach for literature identification and selection prior to its conduct. That is, the approach (or methods) would have been documented *a priori* and provided in the Draft Scope (or a protocol) for comment. As the literature search appears to be completed, no such opportunity was provided to the public.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) stated that it was “unclear if there is, or will be, a protocol (a key element of systematic review) for BD. The scoping document indicates several times throughout that the process described in EPA’s Draft TSCA Systematic Review Guidance Document was followed for BD. The systematic review process described in the guidance includes generation of a protocol” and “[t]he protocol is critical to providing transparency beyond the identification and selection of evidence but also for details of how the evidence will be evaluated – including appraisal of individual studies as well as integrated to develop conclusions. The draft scope does not address the later steps of the risk evaluation and thus it is critical that the methods that will be utilized are described *a priori* in a protocol or in the additional materials that the EPA indicates will be provided.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) stated “In contrast to the principles of systematic review, EPA has not provided a PECO in the Draft Scope” and that “[a] statement defining the purpose of a systematic review needs to specify the Population, Exposure, Comparator, and Outcome of interest. The PECO clarifies the research question and frames the entire exercise.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) stated that the “documentation regarding the search of TSCA submissions is incomplete and does not allow for meaningful public comments” and that additional clarity is needed regarding the search of TSCA submissions. The same commenter provided a list of information of documentation that might assist in this process.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) called the systematic review protocol used in the initial risk evaluations “deeply flawed and has compromised their quality, validity, and protectiveness.” The commenter continued “The SACC has raised numerous concerns about the TSCA protocol, and it is now undergoing review by the National Academy of Sciences Given the many concerns that have been raised and lack of a completed peer review, it would be a serious mistake to use the TSCA protocol in the next round of risk evaluations.” Another commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) stated “since EPA has not published the systematic review documentation before releasing the draft scoping documents, reliance on the Systematic Review here violates the [Administrative Procedures Act] and the Agency’s own regulations governing the scoping process.”

Comment: Several commenters (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049, EPA-HQ-OPPT-2018-0458-0033, EPA-HQ-OPPT-2018-0462-0038) requested that EPA provide more details on its general systematic review approach and process, stating the “first set of scope documents provide little information regarding existing knowledge on potential key hazards, and/or areas of scientific debate to be assessed in the risk evaluation” and should provide significantly more details on the general systematic review approach and process, what will be made publicly with respect to systematic review, and what opportunities there will be for public comment and stakeholder engagement.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) raised concerns related to the level of detail EPA will publish related to systematic review and suggested publication of data sources matched to each condition of use, and a description of relevant data and/or assumptions EPA will rely on when evaluating each condition of use. The same commenter requested that EPA include a list of studies that the agency excluded from risk evaluation for each chemical, while providing an explanation of how it applied systematic review criteria to exclude each study and identifying any relevant data contained therein.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0031) requested that EPA provide adequate time for public comments on the systematic review document after it is published, stating “this additional document and comment period are necessary to ensure all appropriate changes are made in incorporating all public comments on the draft scoping document and the systematic review document.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) commented on studies excluded during systematic review, suggesting that EPA include a list of studies that it chose to exclude from risk evaluation for each chemical, while providing an explanation of how it applied systematic review criteria to exclude each study and identifying any relevant data contained therein. The commenter stated that this would “enhance stakeholder’s understanding of EPA’s

systematic review process, to ultimately promote consistency and transparency in the process. The importance of transparency and consistency here cannot be underestimated as they are foundational elements of TSCA's weight of scientific evidence standard. Further, [the commenter] requests publication about exclusions as early in the process as possible to allow stakeholder engagement." The commenter also suggested allowing an additional comment period, early in the risk evaluation process, allowing stakeholders to comment on data sources and assumptions, once EPA has clearly identified and analyzed data relevant to each condition of use. The commenter stated "Further public engagement would enhance the quality of EPA's risk evaluations and potentially provide additional data sources or considerations."

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) asserted that potentially relevant evidence was identified using a systematic approach and such studies should be considered for eligibility in the TSCA assessment. The commenter stated "Due to the lack of transparency the reporting of the literature search, an independent, protocol-driven search was conducted" and provided a literature inventory of studies should for consideration for eligibility in risk evaluation process for 1,3-butadiene.

Comment: One commenter (EPA-HQ-OPPT-2018-0459-0035) stated "important information like the assessment available from the Canadian Government will not get appropriate consideration – in light of EPA's focus on peer-reviewed literature. Moreover, the criteria the Agency has used for deciding when to include gray literature in its assessment and when to exclude it are not transparent."

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0038) stated "Without a detailed systematic review protocol or analysis plan, it is extremely difficult to evaluate the draft scoping documents as presented. Transparency in EPA's methodology is necessary, given our concerns about EPA's draft systematic review approach." Another commenter (EPA-HQ-OPPT-2018-0433-0034, EPA-HQ-OPPT-2018-0434-0037, EPA-HQ-OPPT-2018-0501-0041, EPA-HQ-OPPT-2018-0503-0032, EPA-HQ-OPPT-2018-0504-0041) stated "EPA inadequately identifies hazard information by omitting systematic review methodology from the Draft Phthalate Scopes."

Comment: A commenter (EPA-HQ-OPPT-2018-0426-0021) asserted EPA must describe circumstances that would merit deviation from the systematic review, or any other process, to consider or exclude any data on a case-by-case basis, noting that the ruling from the 9th Circuit Court of Appeals on *Safer Chemicals Healthy Families, et al v. U.S. EPA* decided that EPA's risk evaluations under TSCA "unambiguously do not grant EPA the discretion" on chemicals' conditions of use.

Response: As described in the scope documents, EPA has initiated the process of searching for, collecting, and screening the data and information for the scopes of the next 20 High-Priority Substances, and will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies' key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions.

The systematic review that is being conducted for the 20 High-Priority Substances is consistent with and builds upon the systematic review conducted for the first 10 risk evaluations. The general tenets of systematic review are well-established and are set forth in EPA's 2018 [Application of Systematic Review in TSCA Risk Evaluations](#) document. The systematic review conducted for the 20 High-Priority

Substances will be reflective of experience gained during the risk evaluation process for the first 10 chemical substances and feedback received from the SACC and public commenters.

In addition, EPA is including in the final scope documents for the 20 chemicals to be undergoing risk evaluation interactive Health Assessment Workspace Collaborative (HAWC) diagrams. These diagrams will present studies that have been screened for inclusion and exclusion for each of the disciplines involved in risk evaluation: engineering, exposure, hazard, fate and physical-chemical properties. In the final scope documents, EPA is including the criteria for inclusion, also known as PECO statements. The PECO statements were developed per discipline with eligibility criteria used in title/abstract and full-text screening.

EPA is also including interactive HAWC diagrams in which the identification numbers will be listed for each study that is found in the EPA Health and Environmental Research (HERO) database in each of the literature categories. Thus, those studies that were tagged as excluded from further evaluation will also be identified within the interactive HAWC diagrams for the public.

EPA always welcomes public participation. The public will have opportunities to comment on the draft systematic review protocol, as well as on each of the draft risk evaluations for the next 20 High-Priority Substances.

Comment: One commenter (EPA-HQ-OPPT-2018-0426-0021) asserted that it is not possible to provide comments on the literature screenings without seeing their methods to understand how they were conducted, referring to the static literature trees in Figures 2-2 through 2-6. The commenter stated “It is inefficient to put this information in a supplemental document, instead of publishing one complete draft scoping document. This will cause EPA staff to write a separate document, and for the public to provide an additional set of comments, meaning that EPA will have multiple rounds of comments on scoping documents at different levels of completeness. This creates extra work and resources for EPA staff and entities following the process.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) stated “The lack of details on the search strategy and search syntax prevents reproducibility” and that “the syntax and approach should be shared as part of the full protocol.” The commenter provided examples of database-specific syntax for consideration.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) mentioned that no inclusion or exclusion criteria are provided, even though Section 2 of the Draft Scope shows that a significant majority of studies were ultimately excluded and that such information is a “key element of systematic review is clearly defining inclusion and exclusion criteria in the protocol. Without them, it is impossible to follow the process and infer what type of studies were in the final inclusion set.” The commenter provided examples of inclusion-exclusion criteria for consideration.

Response: In response to SACC and public comments received during the risk evaluation as well as prioritization processes, EPA plans to publish the “Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances.” This protocol document outlines in detail the current systematic review process EPA is utilizing for the next 20 chemical risk evaluations. EPA will be providing the public with an opportunity to comment on this document.

In addition, EPA is including in the final scope documents for the 20 High-Priority Substances to be undergoing risk evaluation interactive HAWC diagrams. These diagrams will present studies that have been screened for inclusion and exclusion for each of the disciplines involved in risk evaluation: engineering, exposure, hazard, fate and physical-chemical properties. The criteria for inclusion, also known as PECO statements, were developed per discipline with eligibility criteria used in title/abstract and full-text screening. The PECO statements will be included in the scope documents and in the aforementioned protocol document.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026) asserted that EPA has failed to use or mention the future use of a protocol that outlines the pre-established methods to be used throughout the systematic review process as required by EPA regulation under TSCA. The commenter asserted that it is not appropriate that “EPA focuses on the data collection phase during the preparation of the TSCA scope document,” as it should be conducted after the scoping and problem formulation steps are completed, and that EPA fails to explicitly say they will develop and publish a protocol for any of the 20 scoping documents. The commenter also asserted that EPA has had sufficient time to develop protocols detailing the systematic review approaches and/or methods prior to the initiation of the risk evaluation process (it has been two years since EPA released the ‘*Application of Systematic Review in TSCA Risk Evaluations*’). Therefore, EPA has commenced this process without a detailed protocol that is likely to significantly bias these evaluations. The commenter recommended that “In order for EPA to adequately address these issues relating to its lack of transparency, the Agency must immediately implement protocols for each of the Draft Scopes for the High Priority Chemical Substances.”

Response: EPA began data and information collection phase during prioritization in order to inform the prioritization designation. For the TSCA scope documents, the collected studies were screened for relevancy and were categorized to provide information on the data landscape (i.e., data types and amounts) readily available for EPA risk evaluation.

In response to public comments received on the first 10 chemical risk evaluations; the [Application of Systematic Review in TSCA Risk Evaluations](#) document; the prioritization dossiers; the draft scope documents; comments received from the SACC; and the commenter above, EPA plans to publish the “Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances.” This protocol document outlines in detail the current systematic review process EPA is utilizing for the next 20 chemical risk evaluations. EPA will be providing the public with an opportunity to comment on this document.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026) asserted that the approach EPA has proceeded to outline is not consistent with the systematic review process described in the Application of Systematic Review in TSCA Risk Evaluations and contradicts it in fundamental and critical ways. The commenter noted that “In every Draft Scope for the High Priority Chemical Substances, however, EPA states it has already ‘conducted a comprehensive search to identify and screen multiple evidence streams’ and used a PECO (population, exposure, comparator, outcome) statement to assess the eligibility of the included studies before completing the scoping and problem formulation step in the systematic review process.” The commenter expressed concern that “EPA is either not aware of their own explicitly stated method or they have chosen not to adhere to it and inappropriately conducted comprehensive searches of the literature and screened and excluded studies based on PECO’s statement before completing the scoping and problem formulation step.” The commenter recommended that EPA “immediately for each of these Draft Scopes publish: 1) the search strategies used, the list of data bases that have been searched and the dates that the searches were conducted; 2) the PECO statement that has

already been used as the eligibility criteria to include and exclude data sources as EPA does not define what their PECO statement is; and 3) the full list of studies that have been identified for each evidence stream and those that have been excluded at the title and abstract stage.”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) stated “In contrast to the principles of systematic review, the EPA has not made critical information related to the identification and selection of gray literature available in the Draft Scope.”

Response: In response to SACC and public comments received during the first 10 chemical risk evaluations and the [Application of Systematic Review in TSCA Risk Evaluations](#), as well as in response to the prioritization and draft scope documents, EPA plans to publish the “Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances.” This protocol document outlines in detail the current systematic review process EPA is utilizing for the next 20 chemical risk evaluations. EPA will be providing the public with an opportunity to comment on this document.

For the draft scope documents, EPA had conducted peer-review and gray literature searches for each chemical. As outlined in detail in the forthcoming “Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances,” PECO statements were developed per discipline with eligibility criteria used in title/abstract screening. For the final scope documents, EPA will be presenting full-text screening results also based on the corresponding discipline PECO statements. Results will be presented using interactive HAWC diagrams in which the identification numbers will be listed as found in the EPA HERO database for each of the literature categories. The relative distribution of information found in the public literature will be presented via evidence tables.

EPA anticipates that additional literature will be submitted by the public and/or, through literature backward searching or targeted searching for primary data/information. The systematic review process will therefore be an ongoing process as detailed in the “Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances.” Results of the process, including study evaluations, will be published for public comment during the draft risk evaluation.

Comment: Another commenter (EPA-HQ-OPPT-2018-0421-0022) was concerned that “EPA repeatedly refers to yet-to-be-published systematic review documentation to inform EPA’s identification and evaluation of each chemical’s hazards, exposures, and potentially exposed and susceptible subpopulations. Though EPA seems to recognize that the systematic review documentation is relevant and essential for the risk evaluations, EPA’s failure to make this documentation public fails its requirements to make certain information available in the draft scopes. Instead, EPA offers only broad categories of hazards, exposures, and potentially exposed and susceptible subpopulations, and indicates it will only provide specifics once the scopes are finalized. This is not allowed under TSCA and EPA’s regulations.” The commenter recommended that “Because EPA is currently failing its requirements and depriving the public of information necessary to comment effectively on the draft scopes, EPA must publish, and provide adequate time for public comment on, revised draft scopes once the Agency fully identifies the specific hazards, exposures, and potentially exposed or susceptible subpopulations and the reasonably available information EPA relied on to identify them. EPA should also publish and accept comment on its systematic review documentation for each high-priority chemical.”

Response: In response to SACC and public comments received during the first 10 risk evaluations, as well as the prioritization and draft scope processes, EPA plans to publish the “Draft Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances.” This protocol document outlines

in detail the current systematic review process EPA is utilizing for the next 20 chemical risk evaluations. EPA will be providing the public with an opportunity to comment on this document.

In addition, EPA will include in the final scope documents for the 20 chemicals to be undergoing risk evaluation interactive HAWC diagrams. These diagrams will present studies that have been screened for inclusion and exclusion for each of the disciplines involved in risk evaluation: engineering, exposure, hazard, fate and physical-chemical properties. The criteria for inclusion, also known as PECO statements, were developed per discipline with eligibility criteria used in title/abstract and full-text screening. The PECO statements will be included in the scope documents and in the aforementioned protocol document.

Comment: Several commenters (EPA-HQ-OPPT-2018-0446-0034, EPA-HQ-OPPT-2018-0459-0035, EPA-HQ-OPPT-2018-0428-0029, EPA-HQ-OPPT-2018-0444-0028) commented that the draft scopes do not provide the PECO statements for review and comment. Since these statements form the basis of the Agency’s systematic review of the literature, it is critical that stakeholders are aware of, and have an opportunity to provide input to, the criteria the Agency plans to use. Without knowing the selection criteria, it is difficult for commenters to understand the focus of the evaluation and determine whether EPA has identified all of the relevant literature for the evaluation. Although the commenters recognized that the PECO statements are likely written very broadly, strongly encouraged EPA to provide them at each stage of the risk evaluation process to ensure transparency and maximize input from stakeholders.

Response: EPA is including in the final scope documents for the 20 chemicals to be undergoing risk evaluation interactive HAWC diagrams. These diagrams will present studies that have been screened for inclusion and exclusion for each of the disciplines involved in risk evaluation: engineering, exposure, hazard, fate and physical-chemical properties. The criteria for inclusion, also known as PECO statements, were developed per discipline with eligibility criteria used in title/abstract and full-text screening. EPA is also including the PECO statements in the scope documents and in the aforementioned protocol document.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) noted that “Within the literature review, exposure data is captured in two places: engineering and exposure, and it is unclear if or how these areas overlap.”

Response: As defined in Section 2.1.2, engineering refers to information pertaining to environmental releases and occupational exposures. In the context of Section 2.1.2, exposure refers to information on environmental, general population, and consumer exposures.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039) suggested that in the systematic review process EPA publish data sources matched to each condition of use and describe relevant data and/or assumptions EPA will rely on when evaluating each condition of use. The commenter requested that EPA further engage industry by providing information about data sources as early in the scoping or risk evaluation process as possible with an opportunity to comment. The commenter also referenced the scoping document for 1,3-butadiene and stated “EPA identifies data sources for occupational exposure scenarios to include U.S. OSHA Chemical Exposure Health Data . . . program data and U.S. NIOSH Health Hazard Evaluation Reports (p. 42, 1-3 Butadiene Draft Scope). Yet, these sources are unlikely to provide information specific to manufacture or use of paints, coatings, sealants or adhesives. Since studies are not available online, industry cannot evaluate the strength of these sources. EPA’s further analysis prior to risk evaluation is necessary.” The same commenter suggested that EPA include a list of

studies that it chose to exclude from risk evaluation for each chemical and explain of how it applied systematic review criteria to exclude each study and identifying any relevant data contained therein, which would enhance stakeholder's understanding of EPA's systematic review process and, ultimately promote, consistency and transparency in the process. The commenter also requested an additional comment period, early in the risk evaluation process, allowing stakeholders to comment on data sources and assumptions, once EPA has clearly identified and analyzed data relevant to each condition of use.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) claimed the Draft Scope of the Risk Evaluation for 1,3-butadiene, is not compliant with systematic review methods because that draft scope "alludes to a systematic process and the conduct of a systematic review, and includes terms related to components of the initial stages of a systematic review, but the information in the Draft Scope does not comply with systematic review methods." The same commenter urged EPA to "consider data that has been generated since the time it finalized the 2002 IRIS assessment" and provided a list of studies relevant to 1,3-butadiene, such as "numerous studies have been conducted and published that inform mode of action for some of the important effects observed in animals exposed to BD (e.g., ovarian effects observed in mice), more studies informing species differences in metabolism of BD, and an updated epidemiology study of BD workers which also includes a robust exposure reconstruction (exposure matrix)." The same commenter recommended that EPA place greater emphasis on species differences in metabolism, recognize the importance of epidemiology data, and seek to avoid issues/errors in the previous IRIS assessment.

Response: EPA will systematically review all relevant sources including sources pertaining to conditions of use and applicable data. EPA is using the systematic review process described in the [Application of Systematic Review in TSCA Risk Evaluations](#) document to guide the process of searching for and screening reasonably available information, including previous EPA assessments and information already in EPA's possession, for use and inclusion in the risk evaluation. EPA is applying these systematic review methods to collect reasonably available information regarding hazards, exposures, PESS, and conditions of use that will help inform the risk evaluation. For the next 20 High-Priority Substances' scope documents, EPA has completed and presents searches of publicly available literature and the title and abstract and full-text screening of the resultant studies. EPA will subsequently begin the process of data evaluation of the literature. Data evaluation and extraction of data will be done during the risk evaluation phase. EPA identifies critical and supporting studies during the data evaluation phase where quality and relevance are determined. This data evaluation phase is where the studies' key endpoints are carried forward for dose response analysis. Following data evaluation, EPA will organize, extract and synthesize the evidence for each substance and provide a basis for conclusions

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038), in regard to Section 2.4 of the Draft Scope Document for 1,3-butadiene, recommended that mechanistic/mode of action/high throughput studies and biomarker studies be specifically included in the hazards scope.

Response: Studies with mechanistic/mode of action/high-throughput and biomarker information are tagged during title and abstract searching and screening as supplemental information in the systematic review process and remain in scope. EPA plans to conduct full text screening and extract relevant and acceptable information from supplemental information through systematic review methods during the risk evaluation phase if the specific type of supplemental information needed; for example, EPA may fully screen and evaluate mechanistic data for a given chemical for any health hazards (e.g., liver

toxicity) that have been identified for that chemical from the human and animal toxicity studies identifying apical endpoints.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) notified EPA that it is currently compiling relevant and representative industrial hygiene data for 1,3-butadiene from its member companies. These data will include personal and area air concentrations that characterize full-shift and shorter-term task level exposures.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) urged EPA to reconsider use of OSHA CEHD and NIOSH HHE data due to its “age and the targeted nature of the sampling strategies.” They highlight that some of the data pre-dates the 1996 OSHA 1,3-butadiene standard. The same commenter noted for dermal exposure that “[1,3-butadiene] can be liquefied by condensing the gaseous form under high pressure and containing it in vessels that can maintain the necessary pressure. However, rapid evaporation from a pressurized system will cause freezing if it comes into contact with the skin, resulting in frostbite.” Due to the severity of the hazard, the commenter explains that PPE and engineering controls are used. The commenter “does not believe that dermal contact with liquid butadiene would occur except under an extreme accidental circumstance.” The commenter also questioned dermal exposure to liquid waste for workers and use of styrene as a surrogate for 1,3-butadiene exposure data.

Response: Thank you for providing this information. EPA already incorporates temporal representativeness within the data quality criteria during the data evaluation step of EPA’s systematic review process. EPA will consider during the risk evaluation stage the influence of the change of the OSHA PEL between data before and after 1996. EPA has revised the Appendix F for certain conditions of use based on the frost bite concerns with dermal contact with compressed 1,3-butadiene. EPA did not modify the Appendix F table in regard to waste; information submitted through the TRI program indicates waste containing 1,3-butadiene is discharged to wastewater or disposed in landfills. EPA welcomes more data on the waste handling of 1,3-butadiene. EPA appreciates the information on styrene. EPA plans to investigate potential surrogate information, as needed, during the risk evaluation stage.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037, EPA-HQ-OPPT-2018-0438-0054) encouraged EPA to reconsider the use of OSHA CEHD and NIOSH HHE program data because the data are outdated. The commenter stated “although the EPA has limited the exposure data from OSHA’s CEHD to be within the last 10 years, the data were collected as part of compliance inspections and may not be representative of typical employee exposures. OSHA acknowledges that their compliance officers have limited time to conduct an inspection and cannot completely characterize all exposures for all employees and based on their professional judgment often attempt to evaluate worse case chemical exposure scenarios.”

Response: EPA will review all reasonably available data, which includes information from NIOSH and OSHA. These data will be evaluated per the process and metrics presented in the [Application of Systematic Review in TSCA Risk Evaluations](#).

Regulatory Nexus

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034, EPA-HQ-OPPT-2018-0438-0042) stated that EPA lacks the “authority to exclude exposures resulting from these conditions of use” as this is not included in the statutory definitions of conditions of use. The commenter quotes the statute that EPA

must “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical.” The commenter discussed that consideration of other regulatory programs introduces “non-risk factors into the risk evaluation in violation of Sections 6(b)(4)(A) and 6(4)(F)(iii) of TSCA.” The commenter continued that, by excluding certain pathways, EPA would fail to consider all reasonably available information and assess risks to vulnerable subpopulations.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) asserted that EPA must consider all exposure pathways, even where those pathways may be regulated under other EPA statutes. They stated that any such regulations may reduce, but do not eliminate, releases of those chemicals to the environment. The commenter cited EPA’s TRI reporting that shows ongoing emissions to air, water, and land for many of these [next 20 High-Priority Substances] and asserted that if EPA were to exclude known exposures to these substances from their releases via the various pathways, EPA would effectively be assuming that those releases and the associated risks are zero (i.e., non-existent), despite the fact that even the available evidence EPA cited irrefutably establishes that environmental releases at levels well above zero are occurring.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0026) asserted that EPA must examine risks from environmental exposures, including environmental exposures that could be regulated under other laws. The commenter stated that “[r]isk evaluations must . . . examine all sources of exposure that contribute to health and environmental risk . . . regardless of whether other environmental laws might regulate such release to some extent.” The commenter discussed that if Congress had intended a blanket exemption for environmental releases from risk evaluations under TSCA section 6(b), it could have said so explicitly. But not only is there no such exemption in TSCA, its legislative history and structure demonstrate that Congress intended TSCA to provide a comprehensive framework for identifying and managing chemical risks, including those that derive from environmental exposure pathways that are subject to other environmental laws.

The commenter also asserted that EPA’s mandate under TSCA is to ensure that a “chemical substance” does not present unreasonable risk (a determination made without regard to non-risk factors), regardless of how exposure occurs, whereas other statutes do not have that same goal; indeed most environmental laws do not regulate releases based purely on risk.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) asserted that EPA should not exclude incorporation of exposures via pathways that are or could be regulated under environmental statutes such as the CAA, SDWA, CWA, and RCRA. The commenter stated that “TSCA risk evaluations should reflect and incorporate real-world circumstances. Standards and non-regulatory guidance established under these other programs may be years out of date, may be technology-based rather than risk-based, and may not be complied with at all times or in all locations. These pathways add to the aggregate risk of workers and Occupational Non-users (ONUs), consumers and bystanders, and to the general population, including, for instance, more highly-exposed residents near the fence line of point sources. Furthermore, a comprehensive analysis of all pathways of exposure under TSCA may lead to recommendations that a drinking water standard or air standard should be promulgated or updated rather than that a restriction be placed on a chemical’s use through an action under TSCA. Recommendations for action under another statute are an appropriate end result of a TSCA evaluation and are consistent with Section 9 of TSCA.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0048) stated “For each of the 10 initial evaluations, EPA has excluded all environmental release pathways that contribute to human exposure, including air, drinking water, groundwater and soil . . . Because of these exclusions, none of the evaluations addresses exposure by the general population and the contribution of this exposure to overall risk. This approach undermines TSCA’s comprehensive multi-media risk evaluation framework and has been rejected by the SACC because it results in an incomplete and underprotective picture of risk and exposure. The upcoming 20 evaluations must address all environmental releases without regard to other EPA-implemented laws.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049) stated “We also support the decision to exclude potential exposure from ambient air and disposal and soil pathways. As outlined in the Scope, these pathways are addressed through other statutory authorities and do not need to be reviewed under TSCA.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0034, EPA-HQ-OPPT-2019-0131-0045) recommended that the draft scope for each risk evaluation should include consideration of the full life cycle (manufacturing, processing, distribution in commerce, storage, use, and disposal) of each High-Priority Substance, stating: “Life cycle consideration is extremely important, particularly disposal of those chemicals that are not currently regulated under RCRA as hazardous wastes. Due to their unregulated status, these high priority chemicals are at great risk of being improperly disposed at the end of their life cycle and thus causing harm to human health and the environment” and “If the risk evaluations conclude that improper disposal of a high priority chemical presents an unreasonable risk to human health and the environment, EPA should require that the chemical or chemical mixture be properly disposed of at a RCRA-permitted Subtitle C facility.” The commenter also suggested “There already exists a national infrastructure of facilities for the safe disposal of chemical wastes as a result of the RCRA program. For chemicals that pose an unreasonable risk from disposal under TSCA, there is no need for EPA to duplicate the existing requirements for hazardous chemical disposal under RCRA or to promulgate detailed management and disposal standards that are redundant. Likewise, there is no need for EPA to list the TSCA chemicals as hazardous wastes under RCRA because EPA has ample authority under TSCA to require disposal in RCRA Subtitle C permitted facilities.” The commenter also stated “It is worth noting that the most likely scenario for disposal of these chemicals would be in an unlined industrial landfill and thus EPA must evaluate the risk associated with such disposal. Fortunately, EPA already has a risk assessment method for such evaluations. The Delisting Risk Assessment Software (DRAS) was developed by the RCRA office to determine the risk to human health and the environment from the disposal of waste in an unlined landfill or surface impoundment. [The commenter] highly recommends that the agency use DRAS to evaluate the risk to human health and the environment due to improper disposal of these high priority chemicals.” The commenter specifically cited butyl benzyl phthalate, dicyclohexyl phthalate, and di-isobutyl phthalate, HHCB, and TBBPA as chemicals of concern.

Comment: A commenter (EPA-HQ-OPPT-2018-0421-0025, EPA-HQ-OPPT-2018-0433-0037) stated “Because tribes are generally remote, rural, and small populations with lifeways involving multiple local environmental exposures of high duration and frequency, it is clear that federal statute exceptions, variances, local flexibilities, and exclusions – which tend to address these very demographics-- disproportionately affect tribes. In proposing blanket determinations as to whether releases are managed under RCRA, CWA, SDWA, or CAA, EPA is failing in its mission to adequately protect not only the health of tribes, but of other rural, remote, and small populations who essentially fall through the regulatory cracks. Because exceptions for small systems, businesses, and communities are common

throughout federal statute authorities, and tribes use resources in ways that are not considered in granting such exceptions, addressing all primary tribal exposure pathways is critical. The multiple unique ways in which tribes use water and other impacted resources in their environment are not considered or regulated under federal statutes and are indicated in contributing to the environmental health disparities that tribal peoples continue to experience.”

Response: EPA is coordinating action on certain exposure pathways and risks falling under the jurisdiction of other EPA-administered statutes or regulatory programs. More specifically, EPA is exercising its TSCA authorities to tailor the scope of its risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs or risks that could be eliminated or reduced to a sufficient extent by actions taken under other EPA-administered laws. As explained in more detail in Section 2.6.3 of the final scope documents, 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 each of the 20 High-Priority Substances using authorities in TSCA sections 6(b) and 9(b)(1). Clarifying language about what pathways and risks are addressed under other EPA administered statutes or regulatory programs has been added to Section 2.6.3 of the scope documents.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) stated that EPA’s original Maximum Achievable Control Technology (MACT) Standard set emission limits on formaldehyde that would be health protective and EPA undertook an analysis of any residual risk from post-MACT manufacturing emissions and concluded that the risk from mineral wool production was acceptable.

Response: Ambient air releases of formaldehyde from industrial and commercial stationary sources are covered under the jurisdiction of other EPA statutes (specifically the CAA and RCRA) as described in Section 2.6.3. This can be seen in Section 2.6.3.1, 2.6.3.4, and Figure 2.11 in the scope document. Formaldehyde is a listed hazardous air pollutant under Section 112 of the Clean Air Act.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) stated that “[a]ir emissions of 1,3-butadiene from tire manufacturing facilities and the emissions impact on air quality are well regulated pursuant to the Clean Air Act, Tire Manufacturing: National Emission Standards for Hazardous Air Pollutants (NESHAP). 42 U.S.C. §7401. The TSCA bar on redundant regulation of a chemical is directly applicable and bars a risk assessment of the inhalation impact on the general population.”

Response: EPA has determined that the ambient air emissions of 1,3-butadiene are under the jurisdiction of the Clean Air Act and has accordingly tailored the scope of the risk evaluation for 1,3-butadiene. Therefore, ambient air exposures are out of scope.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) stated “Water releases of 1,3-butadiene (BD) are not expected from tire manufacturing. 1,3-butadiene is a volatile substance, any residual amount of 1,3-butadiene in synthetic rubber compounds is low, and [the commenter’s] member tire manufacturing facilities follow best practices to reduce the risk of chemical releases.”

Response: Drinking water exposure is under the jurisdiction of the Safe Drinking Water Act, and EPA has accordingly tailored the scope of the risk evaluation for 1,3-butadiene. Ambient water exposure is in scope. Please provide any supporting data supporting the lack of presence of 1,3-butadiene in water.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) stated air emissions of formaldehyde from tire manufacturing facilities and the emissions impact on air quality are already well regulated pursuant to the Clean Air Act, Industrial, Commercial, and Institutional Boilers and Process Heaters: NESHAP for Major Sources. 40 CFR Part 63 Subpart DDDDD.

Response: Ambient air releases of formaldehyde from industrial and commercial stationary sources are covered under the jurisdiction of other EPA statutes (specifically the CAA and RCRA) as described in Section 2.6.3. This can be seen in Section 2.6.3.1, 2.6.3.4, and Figure 2.11 in the scope document. Formaldehyde is a listed hazardous air pollutant under Section 112 of the Clean Air Act.

However, neither the CAA nor RCRA cover air emissions resulting from consumer activities associated with the installation of products containing formaldehyde which may off-gas formaldehyde following installation. This off-gassing could impact individuals living nearby or adjacent to the residence where the consumer installation activity occurred. Therefore, EPA includes consideration of formaldehyde exposure to co-located or co-residence individuals (and associated potentially exposed or susceptible subpopulations that are co-located or co-residence) due to consumer activities associated with off-gassing from building materials not otherwise addressed within the scope of this risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0042) argued that EPA violated TSCA because it does not plan to include ambient air exposures in the risk evaluation and similarly violates TSCA because the Agency proposes to exclude from the risk evaluation off-gassing exposures from three categories of wood products, because EPA recently issued formaldehyde content regulations for these products. Given the technology-based nature of EPA's rules the commenter stated there will still be formaldehyde emissions and resulting exposures from new products meeting the standards, which EPA would completely ignore. The commenter also stated that existing products in homes continue to off-gas for years after purchase, and laminated products under EPA's regulations are not required to meet the new standards until 2024.

Response: As explained previously in this document and in more detail in Section 2.6.3 of the final scope document, EPA believes it is both reasonable and prudent to tailor TSCA risk evaluations when other EPA offices and programs 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 Title VI. EPA believes that excluding the three regulated composite wood products, as well as laminated products, under TSCA Title VI given their Congressionally mandated emission standards is appropriate in the risk evaluation. Ambient air releases of formaldehyde from industrial and commercial stationary sources are excluded from the scope of this risk evaluation due to regulation by other EPA administered statutes (specifically the CAA and RCRA). This can be seen in Section 2.6.3.1, 2.6.3.2, and Figure 2.16 in the scope document. Formaldehyde is a listed hazardous air pollutant under Section 112 of the Clean Air Act. Additionally, while initial regulations under the CAA are technology based, the CAA also includes requirements to conduct residual risk reviews of all promulgated Part 63 standards to ensure risk posed to public health, welfare, and the environment are addressed. If residual risks are identified, the CAA provides authority to revise existing standards to further protect public health, welfare, and the environment and the associated risks

As noted earlier in the document, EPA is still considering the impact of off-gassing from building products and materials not otherwise addressed to consumers and co-located/co-residence individuals. However, in prioritizing scenarios not addressed by other EPA administered statutes, EPA is excluding a limited group of categorical building products covered by the rule under TSCA Title VI for formaldehyde emission standards for the composite wood panel types identified in the scope document already regulated under TSCA Title VI.

Comment: One commenter (EPA-HQ-OPPT-2018-0444-0028) supported EPA’s decision to exclude potential exposure from ambient air and disposal and soil pathways, stating “As outlined in the Scope, these pathways are addressed through other statutory authorities and do not need to be reviewed under TSCA.”

Response: The Agency agrees with the commenter that in complying with TSCA, EPA may tailor the scope of TSCA risk evaluations in order to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet the statutory deadline for completing risk evaluations.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0038) recommended that additional studies be done to evaluate the risk of formaldehyde release in landfills due to hydrolysis with water and that the landfilling of products made with wood composites (e.g., furniture, cabinets and other furnishings) be evaluated for their potential to leach out formaldehyde in landfills resulting in either formaldehyde gas release, or contamination of drinking water.

Response: EPA excluded formaldehyde releases associated with disposal of material in landfills from the scope of the risk evaluation because such releases are covered under the jurisdiction of other EPA administered statutes (specifically CAA, RCRA, and SDWA) as described in Section 2.6.3. As explained in more detail in Section 2.6.3 of the final scope documents, 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 1,3-butadiene using authorities in TSCA sections 6(b) and 9(b)(1).

Peer Review and the Science Advisory Committee on Chemicals

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) was concerned that “EPA continues to use the same flawed TSCA systematic review process for sorting, selecting, and integrating information for these 20 chemicals as it did for the first 10. [The commenter] urges EPA to discontinue use of this TSCA process until it has been formally peer-reviewed and revised to follow accepted scientific principles. [The commenter] is aware that the National Academies of Sciences . . . has begun its review of the draft guidance ‘Application of Systematic Review in TSCA Risk Evaluations.’ However, this review likely will not be completed before the studies have been selected for these 20 chemical risk evaluations.”

Response: The Agency has taken public comment on its [Application of Systematic Review in TSCA Risk Evaluations](#) document. This framework was used for the first 10 risk evaluations and has been peer-reviewed by the SACC. The lessons learned and recommendations from SACC peer reviews are being incorporated into materials being presented to NAS over a series of public meetings announced for June, July and August 2020. EPA expects a report from NAS later this year. The draft scope documents include results from systematic searching and screening of data sources. The final scope documents include interactive discipline-specific tabular summaries called “heat maps” that categorize the studies by number and characteristics in addition to the graphical literature inventory trees that were provided in the draft scope documents. Most of these evidence maps are now based on full text screening in the final scope documents, whereas the draft scope document evidence map diagrams only included results from title/abstract screening. Study selection occurs during the development of the draft risk evaluation with data evaluation and data extraction. During that phase of the risk evaluation process, EPA will incorporate NAS recommendations to refine our systematic review protocol.

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) asserted: “Assistant Administrator Dunn has expressed interest in eliminating the [SACC] peer review of some or all of the draft chemical evaluations for the next 20 chemicals and others going forward. The agency must engage SACC in public review of the draft evaluations for this next set of chemicals as there are a number of process and substance issues that remain unresolved from the first ten draft chemical risk evaluations. If EPA agrees with [the commenter]’s recommendation to develop risk evaluations on groups of similar chemicals, SACC can function more efficiently as it will have fewer individual chemical review events to plan and execute. It is also imperative that SACC meetings be scheduled after the public comment periods have ended, rather than in the middle of them, so the expert peer reviewers have the full benefit of all the comments. Not all of the public commenters have the capacity or time to prepare substantive and thoughtful comments during the rushed pre-SACC meeting period. Unfortunately, EPA has previously scheduled SACC meetings on risk evaluations before the public comment period has closed for those evaluations. This is not acceptable and, actually, inconsistent with agency-wide peer review guidance.”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0048) stated “Assistant Administrator Dunn has announced that EPA will use a different peer review process for the 20 new evaluations than it used for the first 10 and that the SACC will no longer be reviewing individual evaluations. Any attempt to scale back peer review of the upcoming evaluations would be a serious mistake. Although the SACC process has not been perfect, it has been an essential vehicle for independent scrutiny of EPA’s draft evaluations. Strengths of the process include the involvement of recognized experts, stakeholder input on EPA’s charge questions, direct interaction between SACC members and EPA staff, transparent public meetings, opportunities for the public to submit written comments and make oral presentations, and preparation of a detailed report providing SACC’s findings and recommendations. Since the risk evaluations qualify as Highly Influential Scientific Assessments (HSIA) under EPA and [Office of Management and Budget (JOMB)] guidelines, a robust peer review process containing these basic elements is essential for the next 20 evaluations.”

Response: Assistant Administrator Dunn has repeatedly reinforced and amplified the importance of peer review and public comment in the transparency of the risk evaluation process. EPA is working on schedules for the next 20 risk evaluations and appreciates the commenter’s point about greater lead time for public commenters and has never expressed interest in eliminating the SACC. EPA will continue to conduct peer review on TSCA risk evaluations and adhere to its peer review handbook and OMB guidance on peer review and public comment (see 40 CFR 702.41). Products for peer review

might not meet all of the same criteria that describe crosscutting topics, as suggested by the commenters, including influential and highly influential products. The agency has a tiered approach for peer review of products and is considering peer review of crosscutting topics, tools, models and approaches as recommended by the SACC. These peer review products may or may not meet the same criteria as other products like the current risk evaluation being considered by SACC which are the first of their kind for TSCA. Another suggestion being considered for efficiency is that groups of chemicals may be considered for peer review based upon similar chemistries, COU, exposures and hazards rather than peer reviewing a single chemical risk evaluation at a time.

Confidential Business Information

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) urged EPA to implement the requirements of TSCA section 14 with respect to information on the 20 High-Priority Substances, including timely review of CBI claims. The same commenter asserted that all information constituting health and safety information and not subject to exceptions at 15 U.S.C. § 2613(b)(2) must immediately be made public, including any health and safety information submitted to EPA during the scoping process.

Response: EPA is committed to meeting its statutory obligations, including those in TSCA section 26(j), to make information available to the public relating to the risk evaluation process, including identification of the information and analysis used. EPA generally expects to make the information it uses for decision-making publicly available, consistent with and subject to the requirements of TSCA section 14.

Request for Extension to Comment Period

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0025, EPA-HQ-OPPT-2018-0433-0037) requested an extension to the comment periods for all 20 High-Priority Substances (ending May 26 and June 8, 2020). Another commenter (EPA-HQ-OPPT-2019-0131-0031) requested an extension to the comment period for the group of 7 chemical substances (ending June 8, 2020), given the global COVID-19 pandemic. The latter comment was submitted to the individual dockets for all 20 chemical dockets, as well as the general docket. For convenience, the Agency is treating both comments as applying to all 20 High-Priority Substances. Finally, one commenter (EPA-HQ-OPPT-2018-0451-0037, EPA-HQ-OPPT-2018-0438-0054) also requested an extension to the comment period for 13 of 20 High-Priority Substances per the global COVID-19 pandemic, but also suggested “EPA consider providing additional opportunities to provide data and information on the use of 1,3-butadiene.”

Response: EPA understands that the COVID-19 public health emergency is a rapidly evolving situation. However, as stated in the preamble to the Risk Evaluation Rule, “EPA’s overall objective of this rule is to ensure that it is able to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole. . . . EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines. These same principles will also serve to guide EPA’s implementation of the procedures” (82 FR 33726, 33728 (July 20, 2017)). In order to maintain the Agency’s efforts to adhere to statutory deadlines, EPA will not grant an extension to the current deadlines to submit comments on the draft scope documents.

As to opportunities to provide additional data and information, EPA will continue to gather reasonably available information and will evaluate it following the process outlined in the supplemental documentation on systematic review that will be published during risk evaluation.

General Support for the Risk Evaluation Process

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037, EPA-HQ-OPPT-2018-0438-0054) supported a “robust federal approach for risk evaluations of chemicals.”

Response: EPA appreciates this feedback regarding the risk evaluation process.

Conditions of Use

**Note:* Chemical Abstracts Service Registry Numbers are incorporated in this section for reader convenience and to provide consistency with Conditions of Use elements of the scope documents.

Classification of Conditions of Use

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) criticized the use of the two-tiered classification method used in the Use Report for each chemical, which classifies uses as Tier 1 (“generally have more information to support the accuracy of the use”) and Tier 2 (“may be historic, non-TSCA use, or more anecdotal”). The commenter stated “[t]his division has no support in TSCA, and it cannot be used by EPA to ignore known, intended, or reasonably foreseen conditions of use” and that “TSCA requires EPA to evaluate all of the circumstances ‘under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.’”

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0034) stated that 1,3-butadiene’s (106-99-0) Tier 2 uses include the manufacturing of dyes, use in corrosion inhibitors, use in the manufacture of furniture, and many more; but these uses are not mentioned in the draft scope’s list of 1,3-butadiene’s conditions of use. Most of the uses were classified as Tier 2 because they were substantiated only by international sources, without any evidence that EPA adequately investigated their potential domestic use. The commenter added that EPA should abandon the Tier 1/Tier 2 distinction and evaluate all known, intended, and reasonably foreseen uses in its risk evaluations.

Comment: A commenter (EPA-HQ-OPPT-2018-0434-0035) suggested that in Table 2-2 of di-isobutyl phthalate’s (84-69-5) scope document, the category of Processing – incorporation into formulation, mixture, or reaction product, include an additional subcategory for separate evaluation: Catalyst Component for polyolefins production. The commenter stated “this use is mentioned on Table B-1 in the DIBP Use Report in the Docket (Appendix B, at B-4) but was omitted from the draft scope document. Exposure and release of DIBP in connection with this particular use are well characterized and not significant for health or the environment.”

Response: EPA disagrees with the premise of the comments that suggest EPA has ignored conditions of use based on the Tier 1 and Tier 2 tables of uses that appear in the chemical use reports. The Tier 1 and Tier 2 tables in the chemical use reports are not determinative of conditions of use, but instead were intended to inform EPA’s deliberations on whether conditions of use are known, intended, or reasonably foreseen for each chemical. The tables are intended to capture, in broad strokes, the evidence that may indicate whether activities are “circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of,” per TSCA’s definition of “conditions of use.” This is consistent with the approach described in the Risk Evaluation Rule, which stated “While EPA interprets this as largely a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. . . . In exercising that discretion, for example, EPA

would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's 'conditions of use'" (82 FR 33726, 33729 (July 20, 2017)).

EPA appreciates the comment suggesting the addition of a condition of use subcategory as a Catalyst component for polyolefin production for di-isobutyl phthalate (84-69-5); however, this use is unsubstantiated as Table B-1 in the Use Report for Di-isobutyl Phthalate (CASRN 84-69-5) contains uses classified as Tier 2 and no further evidence was found supporting this use.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) noted that "1,3-Butadiene's Tier 2 uses include the manufacturing of dyes, use in corrosion inhibitors, use in the manufacture of furniture, and many more . . . however, are not mentioned in the draft scope's list of 1,3-Butadiene's conditions of use." The commenter suggested that "[m]ost of them were classified as Tier 2 because they were substantiated only by international sources, without any evidence that EPA adequately investigated their potential domestic use."

Response: Conditions of use were derived from industry reporting to CDR and other documented sources. The Tier 1 and Tier 2 tables in the chemical use reports are not determinative of conditions of use, but instead were intended to inform EPA's deliberations on whether conditions of use are known, intended, or reasonably foreseen for each chemical. The tables are intended to capture, in broad strokes, the evidence that may indicate whether activities are "circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of," per TSCA's definition of "conditions of use." Certain Tier 2 activities were not included in the scope after EPA researched the uses and could not substantiate them as known, intended, or reasonably foreseen, while noting that for Tier 2 uses referenced in Substances in Preparations in Nordic Countries (SPIN), the quantities reported by entire countries for these uses were minimal (falling below the threshold of 0.1 tonnes), compared to the quantities reported by individual companies for Tier 1 uses (sometimes into the millions of pounds).

Comment: Two commenters (EPA-HQ-OPPT-2019-0131-00438, EPA-HQ-OPPT-2019-0131-00439) commented on the categorization of uses in Section 2.2.1 Categories and Subcategories of Use. One commenter (EPA-HQ-OPPT-2019-0131-00438) urged EPA to present the conditions of use "in a clear and consistent manner," and mentioned that "the table for tetrabromobisphenol A (TBBPA) includes categories of use, but they are not reported consistently for triphenyl phosphate (TPP) (115-86-6). EPA should ensure that the tables describing the conditions of use are standardized across chemistries. Additionally, the functional class should be included as part of the description of the condition of use. For example, the TBBPA draft scope document includes description in the use table regarding the function as a flame retardant, but the TPP table does not include this description." The commenter added that "Product and functional use categories are critical steps in the development of exposure estimates."

One of the commenters (EPA-HQ-OPPT-2019-0131-0439) expressed concern that EPA may broadly categorize paints, coatings, sealants and adhesives for evaluation within one condition of use, as either a commercial or a consumer product. The commenter stated that EPA's analysis plan is not clear, leaving open the possibility of evaluating all products generally as one set and that approaching these products as one group does not accurately reflect diversity of product formulations. The commenter was concerned that EPA may issue risk evaluation findings based on availability of certain chemicals, like

phthalic anhydride (85-44-9), in a few specialty products, but which could affect all paints, coatings, sealants and adhesives broadly.

Response: EPA appreciates the commenter's recommendation to present the conditions of use in a clear and consistent manner for all 20 High-Priority Substances in Section 2.2.2 Categories and Subcategories of Use Included in the Scope of the Risk Evaluation. The Agency has made every effort to present conditions of use in a consistent manner using pre-established categories and subcategories of products based on the CDR rule; however, sometimes the categories and subcategories used are different in order to convey the unique conditions of use of each chemical. Also, the Agency agrees that the functional use of chemicals can be useful information to describe a condition of use. For industrial uses, when information is readily available, EPA has also included the functional use as part of the category or subcategory of the condition of use. EPA reviewed the conditions of use tables (Table 2-2) in the draft scope documents for all 20 High-Priority Substances. There are no substantive inconsistencies between the conditions of use for TPP (115-86-6) and TBBPA (79-94-7), only minor wording changes were needed in the TPP table. In addition, for subcategories in the processing rows of the COU Table 2-2 for TPP, EPA added the appropriate functional use category where it was missing in the draft scope document. The scope of the risk evaluation for phthalic anhydride (85-44-9) includes Paints and coatings and Adhesives and sealants among other industrial, commercial, and consumer uses. During risk evaluation, EPA plans to consider the hazard and exposure scenarios for the different uses of phthalic anhydride. EPA plans to also consider specific concentrations of phthalic anhydride in the identified products since EPA uses different modeling and assessment techniques to account for the different product formulations and varying exposures to workers and consumers. EPA acknowledges that there may be uses that present little to no exposure. However, without an evaluation that is unique to the particular chemical's hazard and exposure scenarios, EPA cannot determine whether there is no unreasonable risk associated with these conditions of use.

Comment: A commenter (EPA-HQ-OPPT-2018-0458-0025) stated that the conditions of use in the TPP (115-86-6) scope include use of lubricants, but EPA should "specially identify and evaluate use of [aviation turbine oils (]ATOs[)] in defense and commercial jet turbines and commercial and aeroderivative gas turbine engines (the latter can be non-aviation engines)." Also, the evaluation of TPP in aviation end-uses "should be tailored to the specific circumstances of ATO uses and should not be aggregated with any evaluation of a generic commercial 'lubricants' category, which may involve a range of use assumptions in myriad industries and with exposure and controls circumstances not representative of ATO uses." Substituting a different chemical for TPP would involve "extraordinary costs, years of effort, and disruption of commercial and military aviation operations."

Response: EPA has revised the conditions of use to add two subcategories to Table 2-2 "Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation for TPP (115-86-6)." The first subcategory is for turbine engine oils for use in aviation. The second subcategory is turbine engine oils for use in non-aviation industries.

*Comment: A commenter (EPA-HQ-OPPT-2018-0444-0025, EPA-HQ-OPPT-2018-0446-0035) described the historical uses of *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) in dye manufacturing and reported that, to the best of their knowledge and based on a recent survey done with member companies, "*o*-dichlorobenzene and *p*-dichlorobenzene are not associated with any current or recent use or application in dye manufacturing," nor are the substances present as trace quantities in commercial dyes.*

Response: EPA thanks the commenter for the information. EPA included a condition of use for dye manufacturing in the o-dichlorobenzene (95-50-1) and p-dichlorobenzene (106-46-7) draft scope and final scope documents based on reasonably available information. For o-dichlorobenzene, EPA changed the condition of use from “Processing, Incorporation into formulation, mixture, or reaction product, Pigments in Synthetic dye and pigment manufacturing,” which was in the draft scope document, to “Industrial use, Solvents (which become part of product formulation or mixture) in Synthetic dye and pigment manufacturing” in the final scope document to reflect the submittal by a company of an amended 2016 Form U. For p-dichlorobenzene, EPA changed the condition of use from “Processing, Processing as a reactant, Intermediate in dye manufacturing” which was in the draft scope document, to “Industrial use, Solvents (which become part of product formulation or mixture) in Synthetic dye and pigment manufacturing” in the final scope document based on clarification from industry. EPA considered information assembled from CDR and other sources such as published literature, company websites, and government and commercial trade databases and publications to determine conditions of use. In the 2016 CDR, a company reported the use of o-dichlorobenzene in synthetic dye and pigment manufacturing.

Comment: A commenter (EPA-HQ-OPPT-2018-0446-0034) mentioned plastic material and resin manufacturing uses of p-dichlorobenzene (106-46-7) referenced in Table 2-2 and asks if there are specific plastics or resin products that the EPA will be evaluating.

Response: EPA is evaluating various uses of p-dichlorobenzene (106-46-7) in the plastics manufacturing process (as a reactant or intermediate) and its use in formulations and articles. EPA is considering various plastic or resin types and applications including, but not limited to, an engineering PPS, typically a high-performance thermoplastic.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0051) noted that the draft scope for the risk evaluation of formaldehyde (50-00-0) separately describes (p. 22) “incorporation into an article” as another sweepingly broad condition of use, which is said to encompass the manufacture of “adhesives and sealant chemicals in wood and product manufacturing, plastic material and resin manufacturing (including structural and fireworthy aerospace interiors); construction; [and] paper manufacturing.” The commenter does not believe that the Agency is being clear about how the various subcategories under the larger category will be evaluated.

Response: The Agency used the CDR descriptions to place references in the appropriate categories for the conditions of use. The commenter (EPA-HQ-OPPT-2018-0438-0005) submitted comments noting the use of formaldehyde (50-00-0) in asphalt roofing. The Agency looked to CDR Appendix D guidelines to assist with the placement information the commenter submitted and determined that the Table D.2. Industrial Sector NAICS Code 23, IS Code IS5, IS Title “construction” appropriately captured the commenter’s formaldehyde uses. In the final scoping document, the Agency will clarify that beyond IS Code IS5 “construction” the earlier comment was associated with CDR Consumer and Commercial Product Code C204 Building/construction materials not covered elsewhere and will update the reference in Table 2.2.2 accordingly. The Agency will evaluate subcategories with different exposure scenarios separately; the subcategories are organized together in order to facilitate the link between the category and respective subcategory.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0043) commented that its members produce a diverse range of products falling under the general “conditions of use” EPA has developed for the purpose of risk evaluation. The commenter raised concerns that generalizing exposures by type of

product, (e.g. “paints and coatings” or “sealants and adhesives”) will not result in an accurate risk evaluation for all or even most products associated with a condition of use. For example, the basket “condition of use” of commercial “chemical substances in construction, paint, electrical, and metal products - Adhesives and Sealants; Paint and coatings,” includes a broad range of products. The commenter noted that EPA identifies a similar “basket” condition of use for consumer paints, coatings, sealants and adhesives at page 26 of the formaldehyde (50-00-0) draft scope. The commenter mentioned that EPA has not provided a clear description of how it will evaluate such a diverse condition of use to reach a conclusion of “unreasonable risk” or “no unreasonable risk” for all products within this condition of use. Adding to the complexity of evaluating this condition of use, each product noted as part of this condition of use has several formulations for varying applications. The commenter considered just one product type, “paint and coatings,” in this condition of use by surveying its members for types of paint products that may contain formaldehyde. In response, members identified multiple types of automotive coatings, coil and metal coatings, wood coatings, packaging coatings and specialty coatings.

Response: EPA used the CDR guide to develop the conditions of use categories for this chemical. EPA understands that some of the commenter’s members may use formaldehyde (50-00-0) in different ways, with different end-point applications. Where appropriate the Agency will evaluate the specific conditions of use that reflect the conditions those products are actually used in (e.g., interior commercial, exterior consumer, etc.). In Appendix F and G of the final scope document, EPA maps conditions of use to expected exposure scenarios based on review of preliminary information. After review of the reasonably available information identified through our systematic review process, EPA may further refine the exposure scenarios within conditions of use. As informed by the data, EPA may evaluate exposures across a range of product formulations (e.g., differences in concentrations), application methods, or other similar factors.

Recommended Conditions of Use or Significant Changes in Conditions of Use

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) urged EPA to consider uses of High-Priority Substances that have ceased to be “reasonably foreseen” and to promulgate Significant New Use Rules (SNURs) to require notification prior to any return of such uses to commerce. The commenter stated that “Congress included ‘reasonably foreseen’ circumstances within TSCA’s reach with the express goal of ensuring that EPA swept more broadly than known (or intended) uses; EPA cannot evade that duty by limiting its analysis only to conditions of use with evidence of current, ongoing use—such an interpretation would effectively limit EPA’s analysis to ‘known’ uses.” The commenter asserts that “past conditions of use that are not currently ongoing are ‘known’ to have occurred in the past, and these conditions of use are definitely ‘reasonably foreseen.’” The use of a SNUR then could serve as a “stopgap measure until the risk is evaluated and any needed regulation is implemented.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) referenced EPA’s interpretation of TSCA to exclude discontinued manufacturing, processing and use activities from the definition of “conditions of use.” The commenter states “under section 3(4) of TSCA, ‘conditions of use’ include not simply intended or known uses but the ‘circumstances under which a chemical substance is . . . reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.’ It is clearly ‘reasonably foreseen’ that long-standing and significant uses of a chemical that have been phased out may re-enter commerce in the absence of any legal restriction. The goals of TSCA would be defeated if manufacturers of unsafe chemicals could avoid scrutiny simply by ceasing production for specific uses before EPA completes a risk evaluation and then later re-entering the marketplace free

from any restriction or determination of risk. Recently discontinued uses that may resume should be addressed in the upcoming 20 evaluations.”

Response: EPA agrees that depending on the circumstances, uses of a chemical substance that have ceased may potentially constitute “reasonably foreseen” conditions of use and be included in a chemical risk evaluation. Whether or not a ceased use is “reasonably foreseen” to recur is necessarily a fact-specific inquiry. As EPA explained in the preamble to the Risk Evaluation Rule (82 FR 33726 (July 20, 2017)), “[i]t is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible but, over time under proper conditions, probable.” EPA does not agree that all conditions of use that are known to have ceased are necessarily “reasonably foreseen.”

In regard to promulgating SNURs to require notification prior to the potential return to commerce for a ceased use of a High-Priority Substance, the Agency will consider this approach in concert with its ongoing implementation of the requirements of the Risk Evaluation Rule (40 CFR Part 702), wherein EPA stated its overall objective to conduct timely, relevant, high-quality, and scientifically credible evaluations while ensuring that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0036, EPA-HQ-OPPT-2018-0426-0021, EPA-HQ-OPPT-2018-0428-0026, EPA-HQ-OPPT-2018-0451-0032, EPA-HQ-OPPT-2018-0458-0029, EPA-HQ-OPPT-2018-0462-0033, EPA-HQ-OPPT-2018-0476-0028, EPA-HQ-OPPT-2018-0488-0032) urged EPA to include the uses identified in EPA’s Chemical/ Product Categories Database (CPCat) as conditions of use for 8 of the 20 High-Priority Substances identified including: 1,1-dichloroethane (75-34-3), 1,2-dichloroethane (107-06-2), 1,2-dichloropropane (78-87-5), 1,3-butadiene (106-99-0), TPP (115-86-6), TBBPA (79-94-7), TCEP (115-96-8), and ethylene dibromide (106-93-4). The commenter further explains that “CPCat includes publicly available data only, this list would not include any uses with confidential business information (CBI) classification. CBI uses must be included in the risk evaluation.”

Response: EPA thanks the commenters for the information provided. EPA has reviewed the use information provided and the Chemical/ Product Categories (CPCat) Database for each of the 20 High-Priority Substances and conducted further research to determine if additional conditions of use should be added to the scope documents. Additional details regarding previously identified conditions of use that were identified in the CPCat database and will be considered during the TSCA risk evaluation were also included as part of Appendix E Process, Release and Occupational Exposure Information for the respective chemicals. From the analysis of the information, EPA concluded that the conditions of use presented in the draft scope documents of 1,1-dichloroethane (75-34-3), 1,2-dichloroethane (107-06-2), 1,2-dichloropropane (78-87-5), 1,3-butadiene (106-99-0), TPP (115-86-6), TBBPA (79-94-7), and ethylene dibromide (106-93-4) already included the conditions of use mentioned by the commenter. However, for TCEP (115-96-8), the commenter identified a variety of uses listed on CPCat. EPA examined CPCat as part of development of the scope documents. EPA’s methods for confirming conditions of use in CPCat (and other data bases) included searches in additional databases; review of SDS; outreach with industry, states, trade associations, and academics; as described in the final scope documents. With respect to the specific uses the commenter identified, EPA has not confirmed the use of TCEP in adhesives. CPCat cites Substances in Preparation in Nordic Countries (SPIN) for the use in adhesives, and SPIN removed this use in 2012. The commenter also identifies children’s products as a use listed on CPCat. Based on extensive research and discussion with Washington State Department of Ecology, TCEP has mostly been found in the fabric of children’s products. This use is covered under a

condition of use already identified in the scope document: Foam Seating and Bedding Products. For electronics, transportation equipment (including automobiles and rail cars), and fragrances, the only uses for TCEP found were international sources and these uses cannot be substantiated as conditions of use in the United States.

Comment: A commenter (EPA-HQ-OPPT-2018-0131-0036) identified 1,3-butadiene (106-99-0), DEHP (117-81-7), formaldehyde (50-00-0), and phthalic anhydride (85-44-9) in hydraulic fracturing fluid and DEHP, formaldehyde, phthalic anhydride, BBP (85-68-7), 1,1-dichloroethane (75-34-3), TPP (115-86-6), DBP (84-74-2), *trans*-1,2-dichloroethylene (156-60-5), 1,2-dichloroethane (107-06-2), TCEP (115-96-8), DIBP (84-69-5), *o*-dichlorobenzene (95-50-1), and *p*-dichlorobenzene (106-46-7) in Produced Water (PW) that is generated through oil and gas production. The commenter suggested that EPA include the use and disposal of the listed High-Priority Substances in hydraulic fracturing fluids and produced water as a known or reasonably foreseeable condition of use. The commenter cited an EPA report “*Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States*” and provided four peer-reviewed studies and its own interpretation of a CDR reported use.

Response: As requested by the commenter, EPA has examined the use and disposal of the chemical substances in fracking fluids and produced water as potential conditions of use. As mentioned by the commenter, in 2016, EPA conducted independent research, engaged stakeholders through technical workshops and round tables, and reviewed approximately 1,200 cited sources of data and information. The data and information gathered through these efforts served as the basis for the “*Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States*” report issued by the Agency in December 2016. EPA used this report to inform the decision on whether use and disposal of chemical substances in fracking fluids and produced water constitute conditions of use for the purposes of these scope documents.

In the “Hydraulic Fracturing for Oil and Gas” report, EPA identified the following chemicals as used in hydraulic fracturing fluids: 1,3-butadiene (106-99-0), di-ethylhexyl phthalate (117-81-7), formaldehyde (50-00-0), phthalic anhydride (85-44-9). The draft and final scope documents of these chemicals include a condition of use regarding use in hydraulic fracturing. The report does not indicate that 1,1-dichloroethane (75-34-3) and butyl benzyl phthalate (85-68-7) are used in hydraulic fracturing fluids.

In the “Hydraulic Fracturing for Oil and Gas” report, EPA identified the following chemicals as reported as detected in produced water: 1,1-dichloroethane (75-34-3), butyl benzyl phthalate (85-68-7), di-ethylhexyl phthalate (117-81-7), dibutyl phthalate (84-74-2), TPP (115-86-6). The report does not identify 1,3-butadiene, formaldehyde and phthalic anhydride as known constituents of produced water; therefore, EPA did not intend to identify use or disposal of these three chemicals in produced water in the final scope documents. The “Hydraulic Fracturing for Oil and Gas” report identifies several disposal methods for produced water, which are nearly all covered under the jurisdiction of other EPA-administered statutes and regulatory programs. Most of the produced water (about 93% in 2012) is injected in Class II wells, which are regulated under the Underground Injection Control Program of the Safe Drinking Water Act [42 U.S.C. § 300f; 40 CFR pt. 146, Subpart C]. Hydraulic fracturing wastewater can be used, in combination with fresh water, to make up hydraulic fracturing fluids at nearby hydraulic fracturing operations. Some wastewater treatment facilities treat hydraulic fracturing wastewater and release the treated wastewater to surface water [40 CFR pts. 435.33, 435.34, and 437]. Solid or liquid byproducts of the treatment process can be sent to landfills or injected underground. Evaporation ponds and percolation pits can be used for hydraulic fracturing wastewater disposal [see

40 CFR pt. 257]. Evaporation ponds allow liquid waste to naturally evaporate. Percolation pits allow wastewater to move into the ground, although this practice has been discontinued in most states. Existing federal regulations generally prevent the direct release of wastewater pollutants to waters of the United States from onshore oil and gas extraction facilities east of the 98th meridian [CWA sections 301 and 304; 40 CFR pt. 435.32]. However, in the arid western portion of the continental United States (west of the 98th meridian), direct discharges of wastewater from onshore oil and gas extraction facilities to waters of the United States may be permitted if the produced water has a use in agriculture or wildlife propagation [CWA sections §§ 301 and 304; 40 CFR pt. 435 subpart E].

For the five chemical substances identified by EPA in produced water in the “Hydraulic Fracturing for Oil and Gas” report, the disposal condition of use will encompass all of the above described disposal methods for the produced water. In the conceptual model within the final scopes for “Environmental Releases and Wastes: Environmental and General Population Exposure and Hazards,” the produced water will be included as wastewater or liquid waste (e.g., to account for underground injection) and as solid waste or liquid waste (e.g., to account for landfill disposal and recycling/reuse). EPA added clarifications to the final scope documents regarding the evaluation of pathways from the disposal condition of use, given existing regulations administered by EPA. EPA does not plan to evaluate exposures to the general population or the environment from the aforementioned disposal of produced water, with the exception of the reuse in hydraulic fracturing operations. EPA is exercising its TSCA authorities to tailor the scope of the risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs. 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 and also furthers EPA’s aims to efficiently use Agency resources, avoid duplicating efforts taken pursuant to other Agency programs, and meet the statutory deadline for completing risk evaluations.

The commenter indicated that p-dichlorobenzene (106-46-7), trans-1,2-dichloroethylene (156-60-5), o-dichlorobenzene (95-50-1), 1,2-dichloroethane (107-06-2), TCEP (115-96-8) and di-isobutyl phthalate (84-69-5) are present in produced water. To support this statement, the commenter provides four studies:

- A study that characterizes and analyzes the liquid waste from Marcellus Shale gas development, which was published in 2015 and contains information from wastewater generator reports filed in 2009–2011;
- A study of treatment of the produced waste from the Eagle Ford shale published in 2018;
- A toxicological and chemical study of wastewater from hydraulic fracture and conventional shale gas wells published in 2018; and
- A study of indications of transformation products from hydraulic fracturing additives in shale-gas wastewater published in July 2016.

The commenter also misinterpreted a CDR reported use, claiming that the use as an intermediate in petroleum manufacturing is equivalent to use in hydraulic fracturing. EPA considers the information provided by the commenter as anecdotal and not sufficient to conclude that the findings represent part of the chemical substances conditions of use, since the “Hydraulic Fracturing for Oil and Gas” report prepared by EPA already considered the information presented in two of the studies submitted, and such chemicals were not identified in the final report as constituents in the process water. Further, some of the data included in the studies indicates that the chemicals are found at below detection limits or at a reportable limit.

Therefore, in the final scope no changes were needed to the condition of use representing the use in hydraulic fracturing from the description presented in the draft scope for of 1,3-butadiene, di-ethylhexyl phthalate, formaldehyde and phthalic anhydride. In the final scope of 1,1-dichloroethane and butyl benzyl phthalate, the use in hydraulic fracturing will be removed since these chemicals are only present in the process water. In the final scopes of 1,1-dichloroethane, butyl benzyl phthalate, di-ethylhexyl phthalate, dibutyl phthalate, TPP, “Section 2.6.4 Conceptual Model for Environmental Releases and Wastes” EPA presents exposure pathways, exposure routes, and hazards to human and environmental receptors for releases and waste streams associated with environmental releases from the disposal condition of use, and explains which pathways and exposure routes will not be further evaluated due to other EPA-administered statutes or regulatory programs.

Comment: Another commenter (EPA-HQ-OPPT-2018-0131-0033) indicated that 1,3-butadiene (106-99-0) can be found in hydraulic fracturing fluids. And that 1,1-dichloroethane (75-34-3), *trans*-1,2-dichloroethylene (156-60-5), *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) can be found in produced water following the use of hydraulic fracturing fluids.

Response: EPA appreciates the comments regarding the use of certain high-priority chemicals in hydraulic fracturing and presence in produced water. The draft and final scope documents of 1,3-butadiene (106-99-0) include a condition of use regarding use in hydraulic fracturing. In the final scope document of 1,1-dichloroethane (75-34-3) the use in hydraulic fracturing has been removed, and EPA plans to evaluate the disposal of process water from fracking as part of the disposal condition of use. EPA added clarifications to the final scope document regarding the evaluation of pathways from the disposal condition of use, given existing regulations administered by EPA. Therefore, EPA does not plan to evaluate exposures to the general population or the environment from the injection in Class II wells and other disposal methods, with the exception of the reuse in hydraulic fracturing operations. EPA is exercising its TSCA authorities to tailor the scope of the risk evaluations, rather than focusing on environmental exposure pathways addressed under other EPA-administered statutes or regulatory programs. 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 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. The commenter also indicated that *trans*-1,2-dichloroethylene (156-60-5), *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) can be found in produced water; however, did not provide any additional information to support such statement to be able to consider the information as basis for adding such condition of use to these chemicals. OPPT is using the “Hydraulic Fracturing for Oil and Gas: Impacts from the Hydraulic Fracturing Water Cycle on Drinking Water Resources in the United States” report issued by EPA in December 2016 to inform the decision on whether use and disposal of chemical substances in fracking fluids and produced water constitute conditions of use for the purposes of these scope documents. *Trans*-1,2-dichloroethylene, *o*-dichlorobenzene and *p*-dichlorobenzene were not identified as a chemical used in hydraulic fracturing or present in produced water in the “Hydraulic Fracturing for Oil and Gas” report; therefore, no changes were made to the final scope documents.

Comment: A commenter submitted two comments (EPA-HQ-OPPT-2019-0131-0042, EPA-HQ-OPPT-2019-0131-0051) that identified use information for the following chemicals: TPP (115-86-6), *trans*-1,2-dichloroethylene (156-60-5), 1,3-butadiene (106-99-0), *o*-dichlorobenzene (95-50-1), *p*-dichlorobenzene (106-46-7), 1,1-dichloroethane (75-34-3), 1,2-dichloroethane (107-06-2), 1,2-dichloropropane (78-87-5), ethylene dibromide (106-93-4), HHCb (1222-05-5), TBBPA (79-94-7), 1,1,2-trichloroethane (79-00-5), TCEP (115-96-8), DEHP (117-81-7), phthalic anhydride (85-44-9), DBP (84-74-2), formaldehyde

(50-00-0), BBP (85-68-7), dicyclohexyl phthalate (84-61-7), DIBP (84-69-5). Some of which the commenter claims are critical, for the 20 High-Priority Substances to further inform the scope of each subject chemical.

Response: EPA thanks the commenter for the information provided. EPA has reviewed the use information provided for each of the 20 High-Priority Substances mentioned in the comments. Additional use information provided by the commenter were included as part of the use descriptions in Appendix E Process, Release and Occupational Exposure Information in the final scope documents for the following chemicals: TPP (115-86-6), trans-1,2-dichloroethylene (156-60-5), 1,3-butadiene (106-99-0), o-dichlorobenzene (95-50-1), p-dichlorobenzene (106-46-7), 1,1-dichloroethane (75-34-3), 1,2-dichloroethane (107-06-2), 1,2-dichloropropane (78-87-5), ethylene dibromide (106-93-4), HHCB (1222-05-5), TBBPA (79-94-7), 1,1,2-trichloroethane (79-00-5), TCEP (115-96-8), di-ethylhexyl phthalate (117-81-7), phthalic anhydride (85-44-9), dibutyl phthalate (84-74-2), formaldehyde (50-00-0), butyl benzyl phthalate (85-68-7), dicyclohexyl phthalate (84-61-7), di-isobutyl phthalate (84-69-5). For TPP, EPA has added a use subcategory as “Laboratory chemicals” to the final scope document in the conditions of use Table 2-2 “Categories and Subcategories of Conditions of Use Included in the Scope of the Risk Evaluation for TPP.” EPA will include the condition of use as a component of solid rocket motor insulation in the category of “Processing, Incorporation into a formulation, mixture or reaction product” with a subcategory as “Solid rocket motor insulation” for di-ethylhexyl phthalate in the final scope document. EPA will not include the condition of use as a plasticizer in materials used for tapecasting ceramic powders for dibutyl phthalate at this time. EPA appreciates this information from the commenter but will require additional information on this specific use for dibutyl phthalate to better assess whether it is adequately incorporated by the existing categories of use or requires its own separate categorization of use. EPA plans to follow up with the commenter to ensure this use of dibutyl phthalate is assessed appropriately.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0052) recommended that EPA “quantify and analyze the risk of uses and disposal of plastic made with phthalates, including the foreseeable growth of the production, use, and disposal of these products.”

Response: The Agency’s risk evaluation process relies on volumes of manufacture (including importation) that are reported to the Agency through CDR. These are actual recent volumes. Reporting companies do not forecast future changes, whether increases or decreases, so EPA would need to forecast a trend to use a different volume than that reported. This would be difficult, particularly in the wake of COVID-19 and associated declines in economic activity. While the Agency can observe the direction of trends in past volumes, there is considerable uncertainty forecasting future volumes. Finally, while the commenter asserts that there will be future increases in plastics use generally, this does not necessarily translate to increases in phthalate use.

TSCA requires EPA to conduct risk evaluations to determine whether chemical substances present unreasonable risk under their conditions of use, defined as “the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of.” TSCA sections 3(4), 6(b). Thus, foreseeability is incorporated into the statutory definition of “conditions of use.” However, the term “foreseeable growth” does not appear in TSCA. TSCA does not require EPA to make speculative forecasts of growth or decline in chemical volume; rather, EPA is instructed to “take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use,” which is affected by chemical volume. See TSCA section 6(b)(4)(F)(iv). The statute therefore

does not compel the consideration of speculative fluctuations in chemical volume. Additionally, in most cases, EPA does not have reason to believe that marginally increasing or decreasing the total volume of chemical or the volume of a chemical in a condition of use to account for year-over-year “foreseeable growth of the production, use, and disposal” would change the risk determination. This depends on how exposures are modeled and there is not necessarily a linear relationship between volume of production, use and disposal and related exposure. This is a question of the sensitivity of the risk determination to parameters used in the risk evaluation such as use volume.

Comment: A commenter (EPA-HQ-OPPT-2018-0451-0030) stated that in regard to the condition of use table subcategories “Plasticizer in synthetic rubber manufacturing” and “Solvent in manufacture of synthetic rubber,” to the best of their knowledge, 1,3-butadiene (106-99-0) is used as a raw material or reagent in the manufacture of synthetic rubber. They consider that it cannot be used as a plasticizer and/or solvent in the production of synthetic rubber, due to the intrinsic properties of the substance, which is a gas at room temperature and as a liquefied gas under specific conditions.

Response: After reviewing draft scope document public comments and further analysis, EPA considers the previously-identified “plasticizer” and “solvent in rubber manufacturing” uses as already identified as intermediates in plastic and rubber manufacturing because – based upon physical-chemical properties of 1,3-butadiene (106-99-0) – the chemical could be used as a feedstock in these applications. Also, EPA inadvertently listed “plasticizers in synthetic rubber manufacturing” as a condition of use in the 1,3-butadiene draft scoping document’s Life Cycle Diagram and removed it from the final scoping document because that use was reported to CDR as “plasticizers in plastic material and resin manufacturing” and, as described above, is considered as an intermediate in plastic manufacturing.

Comment: Five commenters (EPA-HQ-OPPT-2018-0488-0028, EPA-HQ-OPPT-2018-0488-0029, EPA-HQ-OPPT-2018-0488-0030, EPA-HQ-OPPT-2018-0488-0035, EPA-HQ-OPPT-2018-0488-0036) explained that ethylene dibromide’s (106-93-4) primary condition of use in the USA is exclusively as part of a fuel additive (typically known as TEL-B) containing tetraethyl lead (TEL) and ethylene dibromide that companies supply into the fuels production industry, predominantly for aviation gasoline manufacture. This TEL-B product contains 35.6% wt. ethylene dibromide.

Comment: Two commenters (EPA-HQ-OPPT-2018-0488-0028, EPA-HQ-OPPT-2018-0488-0030) explained that ethylene dibromide is imported (not domestically manufactured) into the United States as a part of the TEL-B fuel additive. It is one commenter’s understanding (EPA-HQ-OPPT-2018-0488-0028) that there are no EDB production facilities in the USA, and that TEL-B is not sold or provided to the consumer/general public.

Comment: Two commenters (EPA-HQ-OPPT-2018-0488-0028, EPA-HQ-OPPT-2018-0488-0029) mention that a significantly smaller secondary use of ethylene dibromide (106-93-4) is in the production of high-performance racing fuels for a range of gasoline-powered vehicles (less than 10% of total TEL-B use in the USA). According to this commenter, ethylene dibromide contents in such blended racing fuels are typically less than 0.1% wt.

Response: EPA appreciates these comments and has captured these conditions of use in the Scope Document as consumer and commercial uses related to fuels and related products. The conditions of use table also displays that ethylene dibromide (106-93-4) is imported into the United States and not domestically manufactured, as was already captured in the Draft Scope for Risk Evaluation. Although the commenter indicates that TEL-B is not available for consumer use, data reported to the Agency

through the CDR has indicated that ethylene dibromide has a consumer use, likely through a consumer usage of piston aircraft that would require the use of this leaded fuel containing ethylene dibromide. Accordingly, EPA has not removed the consumer use from the final scope document.

Comment: One commenter (EPA-HQ-OPPT-2018-0488-0035) explains that the summary in the Use Report failed to mention that not only do the remaining 35% of the fleet consume the majority of the leaded fuel, but it is this segment of the piston aircraft fleet that is most critical in regards to serving the needs of the transportation infrastructure of the country. The commenter explains that this includes the transportation of essential workers and supplies to the more than 5,000 public use airports across the country and in remote areas of Alaska. The commenter notes that in consideration of the demonstrated impact general aviation has to society and the economy, it is imperative these uses are included in the final Scope of the Risk Evaluation.

Response: EPA is aware that uses of a given chemical – in this instance, ethylene dibromide (106-93-4) – in a sector of the economy can be quite extensive, as the commenter points out. Such instances are included in the Ethylene Dibromide Use Report. EPA has also captured the uses concerning leaded fuels that the commenter mentioned in the scope document as fuels and related products, as was already captured in the draft scope document. However, chemical use reports are not determinative of conditions of use, but instead are intended to inform EPA’s deliberations on whether conditions of use are known, intended, or reasonably foreseen for each chemical. The tables are intended to capture, in broad strokes, the evidence that may indicate whether activities are “circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of,” per TSCA’s definition of “conditions of use. At this point in the risk-evaluation process, EPA’s objective is to identify the conditions of use of ethylene dibromide and then conduct its risk evaluation to determine whether any of the conditions of use as identified in the final scope document for ethylene dibromide, present an unreasonable risk of injury to health or the environment without consideration of costs or other non-risk factors. If it is determined, as a result of the risk evaluation process, that a condition of use presents an unreasonable risk, EPA would then move into risk management and would consider among other things, any impacts to the economy as it determines risk mitigation measures in a TSCA section 6(a) rulemaking. EPA would, of course, consider the points raised by the commenter during this scoping process for the risk evaluation when conducting any necessary risk management.

Comment: One commenter (EPA-HQ-OPPT-2018-0462-0036) stated “The APT process, where TBBPA is used as a flame retardant in “packages,” is conducted outside the U.S. APT facilities migrated outside the U.S. decades ago and are now generally located in southeast Asia (e.g., China, Taiwan, Malaysia, Singapore, Vietnam, Philippines, and Japan). Section E.1.3.5 of the draft scoping document states that one facility in the “Semiconductor and Related Device Manufacturing” sector reported releases of TBBPA to TRI in 2017. The company that reported TBBPA releases to TRI is not [a] member [of the commenter’s organization] and it is unclear whether or not the company is a semiconductor manufacturer.”

Response: During the risk evaluation, the estimated amount used domestically will be investigated for each condition of use.

Comment: One commenter (EPA-HQ-OPPT-2018-0462-0029) commented that estimated production volumes for TBBPA (79-94-7) are high and not consistent with current market trends or dynamics.

Response: The Agency's risk evaluation process relies on volumes of manufacture (including importation) that are reported to the Agency through CDR. These are actual recent volumes as reported to the Agency. The Agency welcomes any additional and more recent data that the commenter could provide.

Comment: One commenter (EPA-HQ-OPPT-2018-0462-0038) pointed out that TBBPA (79-94-7) use in textiles is rare and should be confirmed or excluded from the final scope document. The commenter agrees that the uses of TBBPA reactively in electronics (Printed Circuit Boards) and additively in electronic enclosures are ongoing uses and are the primary uses that should be focused on.

Response: While the use of TBBPA (79-94-7) in textiles may be a limited use, EPA believes there is sufficient information to determine that it is intended, known, or reasonably foreseen, and the Agency did not receive any comments on the draft scope document that would warrant excluding the condition of use from the final scope document.

Comment: A commenter (EPA-HQ-OPPT-2018-0462-0029) suggested that reactive uses (printed circuit boards, brominated epoxy oligomer, Flame Retarded Lexan, and unsaturated polyester resin production) of TBBPA (79-94-7) should be excluded because the TBBPA molecule is reacted into a new molecule. According to an ICL study there is no residual TBBPA after reactive processes. TBBPA used additively in acrylonitrile butadiene styrene (ABS) is manufactured outside the US and the ABS in electronic enclosures forms a barrier from the rest of the appliance; therefore, the TBBPA containing piece does not come into contact with the consumer.

Response: As mentioned by the commenter, TBBPA (79-94-7) is used in reactive uses, and therefore, such use is included in the scope of the risk evaluation. During the risk evaluation, EPA plans to evaluate how much of the TBBPA is found in electronics after reactive or additive uses, as well as the exposure to consumers.

Comment: One commenter (EPA-HQ-OPPT-2018-0462-0030) supports the separation of reactive and additive COUs for electronics. The commenter recommended that in Appendix G, EPA separate the electronic products category to be consistent with separation described previously. Consider clarifying that the reactive flame retardant use is an internal component and the additive FR is an external component.

Response: EPA appreciates the comments, and Appendix G was modified in the final scope to describe the reactive vs additive to TBBPA's (79-94-7) location in an electronic. EPA will consider in the risk evaluation clarifying that TBBPA as a reactive flame retardant is for internal parts of an electronic while TBBPA as an additive flame retardant in electronics can be an external component.

Comment: A commenter (EPA-HQ-OPPT-2018-0462-0034) stated that plasticizer should be considered a reasonably foreseeable use for TBBPA (79-94-7).

Response: Although use as a plasticizer was mentioned in EPA's TSCA Work Plan Chemical Problem Formulation and Initial Assessment for Tetrabromobisphenol A and Related Chemicals Cluster Flame Retardants in 2015, EPA did not include it as a condition of use in the draft scope document for TBBPA (79-94-7) because the only source cited in the 2015 Problem Formulation and Initial Assessment was National Institute of Environmental Health Sciences from 2002, which did not cite any references for this use and EPA could not corroborate the use from any more recent sources. EPA does not believe

there is sufficient evidence that this is an intended, known or reasonably foreseen use of the chemical substance. Therefore, EPA does not plan to consider use as a plasticizer in the risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0462-0036) mentioned that the semiconductors package contains TBBPA (79-94-7); however, TBBPA is reactively combined and becomes one with the polymer matrix. There is no release of TBBPA from the matrix. Cables and transceivers may also contain TBBPA (these articles are imported).

Response: The Agency appreciates the comment and added this as an example further characterizing the electrical and electronic products condition of use in the final scope document COU table for TBBPA (79-94-7). As EPA conducts its analysis during the risk evaluation process, EPA will follow-up with the commenter as necessary to further refine its understanding of the use.

Comment: A commenter (EPA-HQ-OPPT-2018-0458-0025), in regard to ATOs, mentioned commercial additive formulations containing PIP (3:1) also contain a significant proportion of TPP (115-86-6). This combination is an inherent characteristic of the commercial additive manufacturing process and essential to the functioning of ATOs. Therefore, in identifying the conditions of use for TPP for risk evaluation, the Agency should include uses for products offered commercially as PIP (3:1) additives, including use in certain ATOs.

Response: Constituents in the formulation do not typically influence how EPA identifies COUs. If EPA finds information during the risk evaluation that suggests that exposure and releases are different for TPP (115-86-6) containing PIP 3:1, then the Agency plans to prepare appropriate approaches and models for exposure and release estimates.

Comment: One commenter (EPA-HQ-OPPT-2018-0444-0024) provided information on the use of *o*-dichlorobenzene (95-50-1) as a solvent in the manufacture of Pigment Violet 23. The commenter clarified that the substance is not a pigment nor is it an intermediate used to make a pigment. Rather, the commenter said *o*-dichlorobenzene is used as a solvent in pigment manufacturing and requested that EPA eliminate from the scope document any reference to *o*-dichlorobenzene functioning as a pigment. The commenter notified the Agency that the company that reported the function category of *o*-dichlorobenzene as “pigments” in the 2016 CDR recently amended their Form U to report the function category “solvents (which become part of product formulation or mixture).” The commenter also notified the Agency that the company that reported this use in 2016 CDR recently filed a “cessation” notice with EPA stating that it had not imported *o*-dichlorobenzene since March 20, 2019 and committing to not import *o*-dichlorobenzene in the five years following the date of that notice.

Response: EPA appreciates the clarification and has changed the condition of use to reflect broadly the use of *o*-dichlorobenzene (95-50-1) as a solvent rather than as a pigment. Specifically, EPA revised the conditions of use from “Processing, Incorporation into formulation, mixture, or reaction product, Pigments in Printing ink manufacturing, Paint and coating manufacturing, and Synthetic dye and pigment manufacturing” to “Industrial Use, Solvents (which become part of product formulation or mixture) in Printing ink manufacturing, Paint and coating manufacturing, and Synthetic dye and pigment manufacturing” to reflect the amended Form U. EPA removed any reference to *o*-dichlorobenzene functioning as a pigment in the Scope Document and on EPA’s webpage of the risk evaluation of *o*-dichlorobenzene. EPA acknowledges the company filed a “cessation” notice but considers uses reported in 2012 and 2016 CDR as reasonably foreseen conditions of use for *o*-dichlorobenzene.

Comment: One commenter (EPA-HQ-OPPT-2018-0444-0035, EPA-HQ-OPPT-2018-0446-0037) identified ongoing uses of *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) that were not included in the draft scope documents. Specifically, the commenter requested that EPA add use as a chemical processing aid in the manufacture of organic chemicals to the final scope document for the risk evaluation of *o*-dichlorobenzene and add use as a heat transfer fluid in the manufacture of organic chemicals to the final scope documents for the risk evaluation of *o*-dichlorobenzene and for *p*-dichlorobenzene. Additionally, the commenter provided industrial hygiene monitoring data for *o*-dichlorobenzene as a chemical processing aid that was collected at the U.S. manufacturing facility.

Response: EPA thanks the commenter for identifying ongoing uses of *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) and for providing industrial hygiene monitoring data for *o*-dichlorobenzene. EPA added the condition of use “Industrial use, Solvents (which become part of product formulation or mixture), All other basic organic chemical manufacturing” to the final scope document for the risk evaluation of *o*-dichlorobenzene and “Industrial use, Functional fluids (closed system), All other basic organic chemical manufacturing” to the final scope documents for the risk evaluation of *o*-dichlorobenzene and for *p*-dichlorobenzene. EPA will consider the industrial hygiene monitoring data for *o*-dichlorobenzene.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0040) provided a list of additional federal and state regulations for 1,2-dichloroethane (107-06-2) in order to “add more clarification for EPA lists in Appendix D.”

Response: EPA thanks the commenter for this information and for the suggested additions to the list of regulations for 1,2-Dichloroethane (107-06-2). EPA reviewed the federal and state regulations from the list provided by the commenter and updated Appendix D of the final scope document for 1,2-dichloroethane as necessary. EPA notes that Appendix D is not intended to be a comprehensive list of all the federal regulations listed for the 20 High-Priority Substances, rather, it is a high level summary of relevant regulatory actions that inform the conceptual models and EPA’s general understanding of the regulatory universe for the chemical.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0031) clarified whether it uses 1,2-dichloroethane (107-06-2) to manufacture refrigerants at its facilities. The commenter stated that EDC is not used as a raw material at their facilities as indicated in a previous public comment during prioritization (EPA-HQ-OPPT-2018-0427-0015). The commenter concludes that the “material is likely consumed as raw material” by suppliers during the manufacture of products supplied to them for use at their facilities.

Response: EPA appreciates the information provided by the commenter. The information clarifies a public comment submitted during prioritization (EPQ-HQ-OPPT-2018-0427-0015) that identified processors who did not report to EPA. In this instance, the company was identified for processing 1,2-dichloroethane (107-06-2) during the manufacture of blowing agents and refrigerants by the comment submitted during prioritization (EPQ-HQ-OPPT-2018-0427-0015). The comment submitted during the draft scope document (EPA-HQ-OPPT-2018-0427-0031) confirmed that the company does not use 1,2-dichloroethane as a raw material at their facilities. However, the condition of use of “processing as a reactant” remains in the final scope document given the use by other facilities.

Comment: A commenter (EPA-HQ-OPPT-2018-0465-0031) provided information on intent of the product uses for a cable cleaner product that is sold as an aerosol. This is strictly a workplace use product due to the nature of the product use (high voltage cables). The general-purpose degreasing

products are sold as both aerosol and non-aerosol. They are used for heavy degreasing as would occur in an industrial/manufacturing setting, heavy duty transportation maintenance, or utilities. The electrical cleaning product is sold as an aerosol. It is intended for use by professional electrical maintenance technicians. The electronic or precision cleaner products are sold as both aerosol and non-aerosol. They are intended for use by industrial maintenance technicians or electronics professionals.

Response: EPA appreciates the clarification on conditions of use to supplement EPA's understanding on trans-1,2-dichloroethylene (156-60-5) product types and product uses. EPA has updated the descriptions of the conditions of use in the final scope document of trans-1,2-dichloroethylene to reflect that general-purpose degreasers include both aerosols and non-aerosols for industrial and commercial use per the product information provided by the commenter. EPA is retaining the solvents for cleaning or degreasing condition of use for consumers because consumers are expected to purchase and use these products.

Comment: One commenter (EPA-HQ-OPPT-2018-0459-0039) stated that phthalic anhydride (85-44-9) is contained in some specialty adhesives and even more rarely in some specialty industrial coatings.

Response: EPA appreciates comments clarifying phthalic anhydride (85-44-9) conditions of use. These uses were reflected in the April 2020 Draft Scope of the Risk Evaluation for Phthalic Anhydride (1,3-Isobenzofurandione) and are included in the final scope document in Section 2.2.

Comment: One commenter (EPA-HQ-OPPT-2018-0459-0034) disagreed with the COU listing in the phthalic anhydride (85-44-9) draft scope as processing "incorporation into formulation, mixture, or reaction product" and states it should instead be listed "processing as a reactant."

Response: Processing as a reactant or intermediate is the primary use of phthalic anhydride (85-44-9). However, phthalic anhydride Processing- "Incorporation into formulation, mixture, or reaction product" was reported in CDR for the 2012 and 2016 cycles. The manufacturers reporting these uses in CDR provided no comments disputing either the uses or their listing in EPA's April 2020 draft scope document. Accordingly, EPA is not removing this condition of use in the final scope document for phthalic anhydride.

Comment: EPA received a comment (EPA-HQ-OPPT-2018-0459-0034) stating that the Henkel Loctite® 4204 SDS does not list phthalic anhydride (85-44-9) as an ingredient.

Response: SDSs have been identified for Henkel Loctite® 4204 containing phthalic anhydride (85-44-9) in other countries (see link below); however, to avoid confusion, the final draft scope document has been modified to include a reference for a different Loctite adhesive product, Henkel Loctite® 426.

Henkel Loctite® 4204 Great Britain: <https://www.bradechem.com/assets/product-files/Loctite-4204-SDS-bradechem.pdf>

Henkel Loctite® 426: [https://ypsswhdoal-a0d0758e9.dispatcher.hana.ondemand.com/SAP_GATEWAY/odata/SAP/YPSSWH_DOO_SRV/SafetyDataSheetSet\(Appid='YPSSW_SDSUA_EXT',Matnr='229732',Laiso='EN',Rvlid='US',Dmskey=''\)/\\$value](https://ypsswhdoal-a0d0758e9.dispatcher.hana.ondemand.com/SAP_GATEWAY/odata/SAP/YPSSWH_DOO_SRV/SafetyDataSheetSet(Appid='YPSSW_SDSUA_EXT',Matnr='229732',Laiso='EN',Rvlid='US',Dmskey='')/$value)

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0032) stated that they are "not aware of any applications where DEHP (117-81-7) is processed as a 'reactant' or as an 'intermediate.'"

Response: EPA has sources that show the use of di-ethylhexyl phthalate (117-81-7) as a reactant. It was included in reported CDR data, specifically reported as a reactant by at least one company. EPA also found some reported use of it in an SDS from Morgan Advanced Materials. Use as an intermediate was also reported in the most recent CDR. The manufacturers reporting these uses in CDR provided no comments disputing either the uses or their listing in EPA's April 2020 draft scope document. For these reasons, EPA is not removing this use in the final scope document for di-ethylhexyl phthalate.

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0043) noted that the draft scope document included all the conditions of use for dicyclohexyl phthalate (84-61-7) that they were aware of for their customers in the United States. The commenter also explained that certain uses (fabric/textile/leather products, paper products, toys, playground and sporting equipment) need further evaluation to see if such uses are currently being used and questioned the appropriateness of including the scenarios for those conditions of use in the Conceptual Model for Consumer Activities and Uses (Appendix G). The commenter also stated that they are unaware of any uses that are applied via spray or roll application.

Response: EPA thanks the commenter and, in response, further examined those conditions of use. The specific uses the commenter identified, such as paper and textiles, have been recategorized in the table and will now be captured under processing into "Printing ink manufacturing" and "Paint and coating manufacturing." Consumer articles that contain dicyclohexyl phthalate (84-61-7) from inks, coatings and adhesives will now be covered in an "Other" category under the life cycle stage of "consumer use." The specific categories of "Fabric, textile, and leather products not covered elsewhere" and "Paper products" were removed from the table updated as such in the consumer scenarios in Appendix G. In addition, the category of "Toys, playground and sporting equipment" was removed after further review of the report from the Chronic Hazard Advisory Panel on Phthalates and Phthalate Alternatives to U.S. Consumer Product Safety Commission from July 2014. This change is also reflected in Appendix G in the final scope document.

Additionally, during the prioritization process, through research and outreach with industry stakeholders, EPA identified use of spray and roll applications of dicyclohexyl phthalate. In addition, no information was submitted during this comment period to demonstrate that dicyclohexyl phthalate is not applied via spray or roll application, therefore this release/exposure scenario will remain in EPA's final scope document.

Comment: Several commenters (EPA-HQ-OPPT-2018-0438-0031, EPA-HQ-OPPT-2018-0438-0039) asked EPA to state whether their industry specific applications will be included in the risk evaluation scope and asked the Agency to provide specific examples of the types of items and/or exposure scenarios that will be evaluated.

Response: EPA will consider the conditions of use in all of their respective applications in the risk evaluation. This includes industry-specific applications such as automotive, aerospace, marine, industrial, commercial, and consumer uses.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0054) provided an overview of tire materials that are manufactured with formaldehyde (50-00-0). Formaldehyde is not a direct ingredient used to manufacture tires however it is used in the manufacture of three tire materials including resins, coatings on fabric belts and tire mold release agents.

Response: EPA appreciates the comment providing clarity for the use of formaldehyde (50-00-0) in the manufacture of resins, belts, and mold release agents that are later used in the production of tires. The Agency updated the reference the COU table at 2.2.2 to reflect formaldehyde's use in "Processing – Incorporation into an article" for "Plastic material and resin manufacturing"; "Processing – Incorporation into an article" for "Textiles, apparel, and leather manufacturing"; as well as "Processing – Incorporation into an article" for "Rubber product manufacturing."

Comment: The draft scope for the risk evaluation of formaldehyde (50-00-0) references a commenter's (EPA-HQ-OPPT-2018-0438-0051) previous comments in its description of plastic and resin manufacturing; however, the commenter clarified that fiberglass mat production does involve the use of such a resin in the fiberglass mat manufacture.

Response: The Agency used the commenter's original citation (i.e., EPA-HQ-OPPT-0438-0005 from the prioritization of formaldehyde (50-00-0) as a high priority chemical substance) for all of the bullets referenced in E.1.2.2. on the last bullet which references plastic and resin manufacturing in order to streamline the reading of that section. The Agency understands that the commenter submitted information related to the use of formaldehyde-based resins in the manufacture of fiberglass mats; however, the commenter's previously submitted information was used to develop the bullet for "Formaldehyde-based resins used in fiberglass mats."

Comment: Two commenters (EPA-HQ-OPPT-2018-0438-0038, EPA-HQ-OPPT-2018-0438-0044) disagreed with the exclusion of composite wood products in flat panel form from the scope of this evaluation. A commenter believed that the current TSCA VI standard is not providing adequate protection and health information to those people living and working under the conditions of increased temperature and humidity.

Response: Congress set emission standards for specific composite wood products in the Formaldehyde Standards for Composite Wood Products Act of 2010 (see 15 U.S.C. § 2697). EPA believes that in authorizing specific emission standards for the three composite wood products the Congressional intent and result was that formaldehyde emission from these panels and also from component parts and finished goods fabricated from the same panels are appropriately managed under the TSCA Title VI regulatory program.

Comment: Several commenters (EPA-HQ-OPPT-2018-0438-0043, EPA-HQ-OPPT-2018-0438-0037, EPA-HQ-OPPT-2018-0438-0036) stated that composite wood products such as those specifically exempted from EPA TSCA Title VI per Section 770.1(c) (e.g. hardboard, PS-1 rated structural plywood, oriented strand board, etc.) and those "pressed, engineered, or composite" products EPA referenced in the draft scope of the risk evaluation should also be excluded from the final scope for the risk evaluation.

Response: EPA disagrees that composite, pressed, or engineered wood products should be excluded from the risk evaluation with the exception of those three composite wood products that undergo testing and third-party certification under the TSCA Title VI program (i.e., hardwood plywood, medium density fiberboard (MDF) (including thin-MDF), and particleboard). Many of the products that the commenter has identified were exempted from testing and certification by Congress in the 2010 Formaldehyde Standards for Composite Wood Products Act; however, those products do not undergo testing or any type of monitoring by third-party certifiers to ensure that formaldehyde emissions are low. Therefore, the Agency is considering these, and other compressed, engineered, and composite wood products in the

risk evaluation. Likewise, other “pressed, engineered, and/or composite” wood products are not required to go through a testing and certification structure by the EPA.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0037) noted that finished goods constitute a major use of composite wood products. A review of the end uses of panel products underscores the appropriateness of excluding finished goods and construction applications. To include finished goods within the Draft Scope because these downstream products use composite wood panels would eviscerate the exclusion. Panels are rarely used as panels in their end uses. They are typically cut, machined, coated or finished, and incorporated into finished goods and construction. Without language confirming the exclusion extends to those applications, few panels would in fact be covered by the language.

Response: The Agency excluded the three composite wood products (i.e., hardwood plywood, medium-density fiberboard (including thin-MDF), and particleboard) from the scope of the risk evaluation. The scope of the risk evaluation also excludes formaldehyde (50-00-0) emissions from those panels as they are further fabricated into component parts and finished goods. However, to the extent that component parts and finished goods contain formaldehyde from other sources being considered in the scope of the risk evaluation, those products will be considered and appropriately evaluated.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0037) noted that a generic statement should be added to the scope document for formaldehyde (50-00-0) to the effect that materials that do not add formaldehyde emissions when used with excluded composite wood panels in finished goods are not subject to the evaluation. In that instance, only material emitting formaldehyde would be reviewed under the risk analysis.

Response: EPA included in the final scope document of the risk evaluation for formaldehyde (50-00-0) only those conditions of use that contain formaldehyde.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0043) stated that if an impregnated paper, finish, etc. used by a laminated product or finished goods producer contains formaldehyde (50-00-0), then that laminating material or finish should already be included in the scope document as a separate product. In that case, the composite wood panel substrate is exempt, and the laminate/finish is being evaluated separately, so there is no reason to evaluate the laminated product/finished good that simply combines those products together.

Response: EPA believes the commenter is referring to formaldehyde-based resins and/or coatings and not the wood or woody grass veneer that would be added to a certified composite wood product platform to create a laminated product; which, would be regulated as hardwood plywood beginning on March 22, 2024. The manufacture of formaldehyde-based resins and/or coatings will be considered in the risk evaluation; and to the extent that these continue to be formaldehyde (50-00-0) containing chemicals and would be considered throughout their life cycle as they are used and applied to industrial, commercial, and consumer goods.

Comment: Several commenters (EPA-HQ-OPPT-2018-0438-0043, EPA-HQ-OPPT-2018-0438-0046, EPA-HQ-OPPT-2018-0438-0045, EPA-HQ-OPPT-2018-0438-0037) requested clarification in the scope of the risk evaluation for formaldehyde (50-00-0) regarding the definition of the term “panel” or “in panel form” specifically.

Response: EPA believes that the TSCA Title VI definition of a “panel” should apply to the three composite wood products being excluded from the scope of the risk evaluation. And if those panels are excluded from the risk evaluation at that time, then they would continue to be excluded as they are fabricated into component parts and finished goods later in their life cycle. EPA is relying on the definition of a “panel,” “finished good,” “component part,” and “composite wood product” from 40 CFR 770 to define these terms. EPA added definitions of these terms in a footnote in the scope document. EPA is also clarifying that these panels will not be included in the scope of the evaluation in their panel form, or as these panels are fabricated into component parts or finished goods. EPA has determined that other non-TSCA Title VI regulated “composite,” “engineered,” or “pressed” wood products will be included in the scope of this evaluation.

Comment: Several commenters (EPA-HQ-OPPT-2018-0438-0043, EPA-HQ-OPPT-2018-0438-0041, EPA-HQ-OPPT-2018-0438-0045, EPA-HQ-OPPT-2018-0438-0037) requested that laminated products and finished goods made with composite wood panels be excluded from the scope of the risk evaluation for formaldehyde (50-00-0).

Response: EPA agrees with the commenter that TSCA Title VI regulated composite wood products and downstream products (i.e., component parts and finished goods) that only contain TSCA Title VI certified composite wood products should be excluded and clarified the final scope document for the risk evaluation. However, to the extent that those finished goods referenced by the commenters contain non-TSCA Title VI-regulated composite wood, engineered, or pressed wood products and/or formaldehyde (50-00-0) containing chemical substances that are in the scope of the risk evaluation they would be evaluated.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0050) recommended that EPA update the references to reflect a corrected meeting date. The EPA hosted the commenter for a meeting on November 18, 2019. Please correct the listing in the References Section to read: “Meeting. (November 18, 2019). Meeting with EPA and [the commenter].” Also, the meeting was attended by member companies that were identified in the slide deck.

Response: EPA will make the necessary correction to show the correct meeting with the commenter.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0050) recommended that the EPA consider whether the reference for Enthone-OMI, Inc. (1990) could be better characterized in Table 2-2 given that this document addresses electroless copper processes. Currently, this reference is cited under both commercial and consumer uses of chemical substances in electrical products

Response: EPA appreciates the comment regarding the risk evaluation process and updated the reference to reflect the appropriate condition of use.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0037) requested that solid wood, in any form, not be included within the scope of the risk evaluation.

Response: EPA has not included naturally occurring formaldehyde (50-00-0) from virgin timber in the scope of the risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0050) asked EPA to revise the condition of use in Table 2-2 Categories and Subcategories of Conditions of Use. Formaldehyde (50-00-0) is a reducing

agent that is not incorporated into electronics for consumer and commercial uses and, therefore, the EPA should recharacterize this use to a more accurate and appropriate life cycle stage, category, and subcategory. The “[the commenter] Meeting (2019)” reference should be linked with the new characterization of the condition of use. The commenter suggests the most accurate characterization is as a non-incorporative activity because the process uses formaldehyde as a chemical processing aid that does not become part of the end product or article.

Response: EPA will characterize the commenter’s use in the specific condition of use for formaldehyde (50-00-0) used as a reducing agent during the production of electrical and electronic products, including semiconductors.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0037) suggested that EPA enumerate the substantial resources that have been invested in creating an effective framework for regulating formaldehyde (50-00-0) in composite wood products through the Formaldehyde Standards Regulations, as well as the substantial benefits that are achieved from relying on those existing requirements to protect against potential risks.

Response: EPA agrees with the commenter and has excluded from the scope document the composite wood products that are regulated under the TSCA Title VI program.

Byproducts, Impurities, Residuals, De Minimis, and Contaminants

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) urged EPA to analyze all conditions of use, including any presence as a byproduct, impurity or contaminant, and any metabolites or degradation products, in its risk evaluations of the high priority substances. The commenter stated “As EPA begins the risk evaluations for the 20 high-priority chemicals, EPA must consider all ‘conditions of use’ of the chemical substances. 15 U.S.C. §2605(b)(4)(D). ‘Conditions of use’ expressly includes ‘the circumstances [. . .] under which a chemical substance is intended, known, or reasonably foreseen to be to be manufactured, processed, distributed in commerce, used, or disposed of.’ 15 U.S.C. § 2602(4). Circumstances where any of the 20 high-priority chemicals substances are present as byproducts, impurities or contaminants, or where the chemical substances give rise to metabolites or degradation products, are ‘known’ or ‘reasonably foreseen’ ‘manufacture,’ ‘process[ing],’ ‘use,’ or ‘disposal of’ the chemical substance. Congress expressly chose to define ‘conditions of use’ broadly to include not only ‘intended,’ but also ‘known’ or ‘reasonably foreseen’ manufacture, processing, distribution, use, and disposal. 15 U.S.C. § 2602(4). Disregarding chemical substances when present as impurities or byproducts, for example, because their presence is not ‘intended,’ essentially would read the other two scenarios out of the statute.”

Response: EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as a byproduct, impurity or contaminant in another chemical substance that is not the subject of the pertinent scoping. In some instances, it may be most appropriate from a technical and policy perspective to evaluate the potential risks arising from a chemical present as a byproduct, impurity or contaminant within the scope of the risk evaluations for the chemical substance itself. In other cases, it may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the byproduct, impurity or contaminant. In still other cases, EPA may choose not to include a particular byproduct, impurity or contaminant within the scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the chemical substance would be de minimis or otherwise insignificant. See “Procedures

for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act” (82 FR 33726, 33730 (July 20, 2017)).

Comment: A commenter (EPA-HQ-OPPT-2018-0451-0027) stated that their data submission will allow EPA to conclude that the use of 1,3-butadiene (106-99-0) in the manufacture of synthetic rubber is safe and that consumer exposure to 1,3-butadiene from synthetic rubber is negligible.

Response: EPA plans to evaluate the information that the commenter provided as it moves through the risk evaluation process. In particular, EPA plans to analyze the 1,3-butadiene (106-99-0) residual range amount values in the final manufacturing product as the Agency evaluates potential exposure to consumers, and as EPA conducts its analysis it will work to determine the mechanism by which 1,3-butadiene leaches out of synthetic rubber. As necessary, EPA will follow-up with the commenter to further discuss their data. The Agency also plans to consider facility exposure data from the manufacturing process during the risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0451-0038) provides information for many conditions of use. For “Processing aids, not otherwise listed in: Petrochemical manufacturing,” the commenter states that to the best of their knowledge, the chemical is not added or used as a processing aid within any petrochemical manufacturing operations. They state that following the distillation/refinery process, 1,3-butadiene (106-99-0) is found in concentrations below 0.5% in liquefied petroleum gas and that no 1,3-butadiene is found in gasoline or other liquid fuels above 100 ppm. The commenter also states that there appear to be only residual amounts of 1,3-butadiene in the following conditions of use scenarios that involve reactants and monomers: “processing in adhesive manufacturing, paints and coatings manufacturing, petroleum lubricating oil and grease manufacturing, and all other chemical product and preparation manufacturing,” “processing as polymer in rubber product manufacturing,” “industrial use in adhesives and sealants, and processing aids, specific to petroleum production,” “commercial use of plastic and rubber products not covered elsewhere, automotive care products, lubricants and lubricant additives, paints and coatings, and adhesives and sealants,” and “consumer use of plastic and rubber products not covered elsewhere.”

Response: The Agency appreciates the information provided regarding the levels of 1,3-butadiene (106-99-0) in gasoline; however, in order to be able to utilize the information during risk evaluation, additional documentation of the 100 ppm level mentioned by the commenter would be needed, such as how representative the data is of most petrochemical companies and the analytical methods used to generate the data. With respect to the residual amounts of 1,3-butadiene in reactants and monomers, during risk evaluation, EPA will consider the concentrations and the stability of 1,3-butadiene in the products identified by the commenter, since the Agency can incorporate the weight fraction of a given chemical into exposure models.

Comment: A commenter (EPA-HQ-OPPT-2018-0451-0033) stated that in regard to EPA noting that 1,3-butadiene (106-99-0) is not expected to degrade to the 1,3-butadiene monomer, EPA must further evaluate such degradation potential and cannot ignore it on the basis provided in the draft scope.

Response: EPA will consider any information concerning degradation and leaching of 1,3-butadiene (106-99-0) monomer and based on such information, during risk evaluation EPA will determine whether the amount of degradation and leaching is negligible.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) stated that synthetic polymers may contain residual 1,3-butadiene (106-99-0) as an impurity and that the 1,3-butadiene monomer comprises an insignificant mass in the overall composition of a finished tire, and cannot be created from the use of synthetic rubber in the manufacture of a tire because once polymerization has occurred, it is nearly impossible to break the polymer chain back into individual units of 1,3-butadiene.

Response: EPA plans to analyze information related to residual monomer amounts in products and potential for degradation of the products during the risk evaluation process.

Comment: Another commenter (EPA-HQ-OPPT-2018-0444-0026, EPA-HQ-OPPT-2018-0446-0028) identified two products they manufacture that contain *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) and provided information on the use of these products as fuel additives and lubricants for engines and tools, the *de minimis* volumes of *o*-dichlorobenzene present in the formulas, and the Tier 1 Testing performed on one product to be registered under EPA as a fuel additive. The commenter suggests *p*-dichlorobenzene may be a contaminant of *o*-dichlorobenzene but indicated they have no test results that show the presence of *p*-dichlorobenzene in the products. The commenter believes that the products “pose no risk to either health or the environment” and “should be excused from participation in further EPA risk evaluation activities and potential additional regulation.”

Response: EPA appreciates the commenter’s information. The scopes of the risk evaluations for *o*-dichlorobenzene (95-50-1) and *p*-dichlorobenzene (106-46-7) include processing of the substances as solvents in lubricant and fuel additive formulations and the commercial and consumer uses in lubricants and greases and in fuels and related products. During risk evaluation, EPA will consider the hazard and exposure scenarios for the different uses of *o*-dichlorobenzene and *p*-dichlorobenzene. EPA plans to consider concentrations of *o*-dichlorobenzene and *p*-dichlorobenzene in the identified products since EPA uses different modeling and assessment techniques to account for the different product formulations and varying exposures to workers and consumers. Pursuant to EPA’s procedural rule for chemical risk evaluation under TSCA, EPA’s risk evaluations are “fit-for-purpose,” such that all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk (see 82 FR 33726, 33734, 33739-40 (July 20, 2017)).

Comment: A commenter (EPA-HQ-OPPT-2018-0444-0028) suggested that EPA drop consideration of commercial and consumer uses in the risk evaluation that have residual levels (less than 1%) of *o*-dichlorobenzene (95-50-1), as potential exposure to the chemical substance is low. The commenter explained that “much of the information on the consumer uses . . . appears to reflect the potential presence of residual levels of 1 percent or less in finished products. The same is true for some of the identified commercial uses.”

Response: EPA thanks the commenter for the suggestion. EPA is retaining within the scope of the risk evaluation the commercial and consumer conditions of use for products that appear to have residual levels of 1% or less of *o*-dichlorobenzene (95-50-1) in finished products. EPA plans to consider specific concentrations of *o*-dichlorobenzene and its relative stability in identified products and plans to evaluate the residual amounts of *o*-dichlorobenzene in conditions of use since EPA uses different modeling and assessment techniques to account for the different product formulations and varying exposures to workers and consumers. Pursuant to EPA’s procedural rule for chemical risk evaluation under TSCA, EPA’s risk evaluations are “fit-for-purpose,” such that all conditions of use will not warrant the same level of evaluation, and EPA expects that it may, in some cases, be able to reach

conclusions without extensive or quantitative evaluations of risk (see 82 FR 33726, 33734, 33739-40 (July 20, 2017)).

Comment: A commenter (EPA-HQ-OPPT-2018-0446-0034) highlights the use of *p*-dichlorobenzene (106-46-7) in high performance plastics and underscores that *p*-dichlorobenzene is “completely consumed in the manufacturing process and the chlorine is removed as a byproduct.” The products in which the high-performance plastics are used include appliances, car parts and machines not in household products or single use applications. The commenter asks if there are specific plastics or resin products EPA plans to evaluate. The commenter also recommends EPA exclude exposure to residual *p*-dichlorobenzene in plastics manufacturing, disputing an industry document that there may be up to 100 ppm residual *p*-dichlorobenzene in a plastic product.

Response: EPA appreciates the commenter’s detailed comments. EPA is retaining in the final scope document the conditions of use for *p*-dichlorobenzene (106-46-7) in plastic material and resin manufacturing and in plastic product manufacturing based on several CDR reports on various uses of *p*-dichlorobenzene in plastic material and resin. The commenter also recommends that EPA exclude exposure to residual *p*-dichlorobenzene in plastics from the risk evaluation. EPA plans to consider specific concentrations of *p*-dichlorobenzene and its relative stability in identified products and plans to consider residual amounts of *p*-dichlorobenzene in conditions of use based on reasonably available information on concentrations of *p*-dichlorobenzene in products. EPA uses different modeling and assessment techniques to account for the different product formulations and varied exposures to workers and consumers.

Comment: A commenter (EPA-HQ-OPPT-2018-0426-0025, EPA-HQ-OPPT-2018-0465-0037, EPA-HQ-OPPT-2018-0421- 0027) requested that EPA’s final scoping documents for 1,1-dichloroethane (75-34-3), 1,1,2-trichloroethane (79-00-5), and *trans*-1,2-dichloroethylene (156-60-5) differentiate intentional production scenarios from the unintended generation of impurities as separate conditions of use. The commenter states this will properly consider the conditions of use of the High-Priority Substances as unintended byproducts in the manufacture of 1,2-dichloroethane (107-06-2) and their subsequent conversion to other intermediates.

Response: EPA will address on a case-by-case basis circumstances where the chemical substance subject to scoping is unintentionally present as an impurity, or as a byproduct, resulting from a process for another chemical substance. In this instance, EPA is including additional language in the final scope documents indicating that the byproducts, 1,1-dichloroethane (75-34-3), 1,1,2-trichloroethane (79-00-5), and *trans*-1,2-dichloroethylene (156-60-5) formed during the manufacture of 1,2-dichloroethane (107-06-2) will be addressed in the 1,2-dichloroethane risk evaluation. EPA believes that the regulatory tools under TSCA section 6(a) are better suited to address any unreasonable risks that might arise from these activities through regulation of the activities that generate 1,2-dichloroethane than they are to addressing them through direct regulation of 1,1-dichloroethane, 1,1,2-trichloroethane, or *trans*-1,2-dichloroethylene.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0034) stated that EPA should “presume presence of 1,2-dichloroethane (107-06-2) in end products,” and referenced the draft scope for 1,2-dichloroethane where EPA states “it has received comments that manufacturers have identified residual amounts of the chemical in end products, however, formulators are uncertain how much remains in these products from the residuals in raw materials (EPA-HQ-OPPT-2018-0451-0005). Because of this uncertainty; EPA plans to evaluate these conditions of use.”

Response: EPA appreciates the comment requesting the Agency to presume presence of 1,2-dichloroethane (107-06-2) in end use products. EPA referenced information submitted by commenters in the draft scope documents and considered reasonably available information, including public comments, when determining the conditions of use for the draft scope document. The final scope document includes industrial use of adhesives and sealants as well as commercial and consumer use of plastic and rubber products; therefore, such end uses will be evaluated during risk evaluation.

Comment: A commenter (EPA-HQ-OPPT-2018-0427-0040) urges EPA to consider the evidence of the lack of 1,2-dichloroethane (107-06-2) in finished PVC resins and products.

Response: EPA appreciates the evidence submitted by the commenter regarding residual 1,2-dichloroethane (107-06-2) in finished PVC resins and products. Given the evidence submitted to the Agency by the commenter ([EPA-HQ-OAR-2002-0037-0203](#)) regarding residual amounts of 1,2-dichloroethane in PVC resin, commercial and consumer plastic and rubber products, such use is included in the final scope document and the information provided by the commenter, along with other reasonably available information, will be evaluated as part of the systematic review process. This process will inform the approach EPA will take to evaluate this use to account for the amount of 1,2-dichloroethane in the commercial and consumer plastic and rubber resins and products.

Comment: Multiple commenters (EPA-HQ-OPPT-2018-0459-0039, EPA-HQ-OPPT-2018-0459-0035, EPA-HQ-OPPT-2018-0459-0034) expressed concern over EPA's inclusion of certain phthalic anhydride (85-44-9) commercial and consumer uses, stating that phthalic anhydride is processed as a reactant and that it is typically consumed in the reaction and not available in downstream products or uses. One commenter (EPA-HQ-OPPT-2018-0459-0034) stated that phthalic anhydride is "not used directly in any of the applications listed; however, derivatives or reaction products such as ortho-phthalates may be present in the product types listed. The scope document must distinguish between the use of phthalic anhydride itself from products made using phthalic anhydride." The commenter (EPA-HQ-OPPT-2018-0459-0034) provided an example, stating "ortho-phthalates made from phthalic anhydride are used in these applications, but unreacted phthalic anhydride is not."

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0039) stated that "phthalic anhydride is not present in alkyd polymer resins, the raw material used during paint and adhesive formulation." This commenter (EPA-HQ-OPPT-2018-0459-0039) also states that phthalic anhydride is a reactant and no longer exists as an identifiable material once the alkyd polymer has been manufactured. The commenter (EPA-HQ-OPPT-2018-0459-0039) makes the point that phthalic anhydride is not used directly as an ingredient in the formulation of paints and coatings; it is used in polymer manufacture, the product of which is a component used in paints and coatings.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0035) discussed similar points to the first two and recommends to EPA that "those conditions of use related to the incorporation of phthalate esters, resins, dyes, and pigments into finished products, as well as the commercial and consumer use of those finished products, be removed from the scope of the risk evaluation."

Comment: EPA received one comment disagreeing with the previous commenters regarding phthalic anhydride's (85-44-9) presence in downstream uses. The commenter (EPA-HQ-OPPT-2018-0459-0036) stated "EPA cannot assume that an identified use as an intermediate results in negligible release or exposure. The chemical may remain in downstream reaction products or in the final product as a residual due to, for example, incomplete reactions. These residuals can be present in significant amounts

in certain cases and there can be variation in the extent to which they are present over time, in different batches, or among different producers and processors. This variability should be considered when evaluating potential risk.”

Response: EPA appreciates the comments drawing attention to this issue. We recognize that phthalic anhydride (85-44-9) is used primarily as an intermediate to make other chemical products. For this type of use as a reaction intermediate, we agree with the commenters that the expectation is that phthalic anhydride would be reacted away and not become part of the reacted product, which could then become part of commercial products such as coatings. However, EPA intends to investigate this further in the risk evaluation to gather information on the residual amount of phthalic anhydride or its hydrolysis product, if any, in commercial products that contain reaction products produced from the use of phthalic anhydride as an intermediate.

Given the potential for residual phthalic anhydride or its hydrolysis product and that no data was submitted during this comment period to demonstrate that phthalic anhydride or its hydrolysis product is not present in downstream uses, these uses remain in EPA's final scope document. EPA is providing additional narrative in the final scope document to address commenters' concerns over the lack of clarity regarding what phthalic anhydride is used to produce and what products are made using phthalic anhydride in formulation. These descriptions can be found in Appendix E: PROCESS, RELEASE AND OCCUPATIONAL EXPOSURE INFORMATION.

Legacy Uses

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) stated “EPA has not identified whether legacy uses exist for any of these 20 [High-Priority Substances, despite the fact that several of the chemicals have the potential for such uses.” Another commenter (EPA-HQ-OPPT-2018-0421-0025, EPA-HQ-OPPT-2018-0433-0037) described the disproportionate effect not considering legacy uses could pose to tribes’ exposures, including how “[o]lder electronics, furniture, and thrift store purchases can lead to continued and chronic exposure to toxins inside people’s homes” and urged EPA to consider the impacts of legacy use of all 20 High-Priority Substances chemicals on tribal populations.

*Comment: One commenter (EPA-HQ-OPPT-2019-0131-0048) referenced the Ninth Circuit decision in *Safer Chemicals v. United States EPA*, 943 F.3d 397 (9th Cir. 2019), and asserted “EPA’s risk evaluation framework rule does not grant the agency discretion to exclude conditions of use from the scope of risk evaluations. Accordingly, EPA must address all conditions of use in the upcoming 20 evaluations.” The same commenter stated “In upcoming risk evaluations for the 20 high-priority substances, EPA must address all ongoing uses of legacy products and associated disposal activities. There is no evidence in the draft scopes that EPA is systematically attempting to identify these products and activities.” Another commenter (EPA-HQ-OPPT-2019-0131-0032, EPA-HQ-OPPT-2019-0131-0043) added “EPA has not identified whether legacy uses exist for any of [the] 20 [High-Priority Substances], despite the fact that several of the chemicals have the potential for such uses” and “Absent this step, the risk evaluations will be incomplete and non-compliant with the requirements of the Risk Evaluation Rule.”*

*Response: As a result of the Ninth Circuit Court of Appeals’ decision in *Safer Chemicals, Healthy Families v. U.S. EPA*, 943 F.3d 397, 425 (9th Cir. 2019), EPA is no longer excluding legacy uses (i.e., circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) or associated disposal (i.e., ongoing disposals from legacy uses) from the*

definition of “conditions of use.” Rather, when these activities are intended, known, or reasonably foreseen, these activities are considered uses and disposal, respectively, within the definition of “conditions of use.”

Regarding exposures to tribal populations, “potentially exposed or susceptible subpopulations” could include subpopulations with unique exposure circumstances, such as tribes, and relevant PESS will be considered as part of the risk evaluation process for each of the High-Priority Substances. In addition to requirements under TSCA regarding “potentially exposed or susceptible subpopulations,” the Agency is committed to consultation and coordination with Tribes (see the EPA Policy on Consultation and Coordination with Indian Tribes available at <https://www.epa.gov/tribal/forms/consultation-and-coordination-tribes>).

Non-TSCA Uses

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0040) requested that the scope documents consider uses such as “pesticides” and “personal care products.” Another commenter (EPA-HQ-OPPT-2018-0430-0028) asserted that an exclusion of “cosmetics” under TSCA should extend to exclude from the scope of risk evaluations the use of HHCb as an ingredient in manufacturing a cosmetic.

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0034, EPA-HQ-OPPT-2018-0434-0037, EPA-HQ-OPPT-2018-0501-0041, EPA-HQ-OPPT-2018-0503-0032, EPA-HQ-OPPT-2018-0504-0041) found that EPA’s plan for risk evaluation underestimates risk due to the failure to consider background exposures to “non-TSCA uses.” The commenter noted that “EPA itself acknowledges that all of the High-Priority Phthalates have non-TSCA uses, including uses in dental sealants, fragrances, baby products, pharmaceuticals, cosmetics, nail polish, pesticides, fumigants, and a variety of food packaging substances including cellophane, plasticizers in polymeric substances, and paper and paperboard components intended to contact dry food or fatty foods. These uses are not only varied, but make up a substantial share of phthalates’ use in general.” The commenter continued “While EPA is only mandated to conduct a risk assessment for TSCA conditions of use, EPA must still account for non-TSCA uses as background exposures when evaluating whether conditions of use EPA does consider present unreasonable risk. This is because it is impossible to determine if the conditions of use that TSCA does regulate present an unreasonable risk if non-TSCA uses that contribute to a baseline level of phthalates in the human body are ignore” and “EPA’s explicit plan to exclude from consideration uses of the High-Priority Phthalates subject to statutes such as the Federal Food Drug and Cosmetics Act ignores the reality of human exposure.”

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0041) recommended EPA exclude medical devices and their components, drug-device combinations and food contact articles, from the scope documents.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0033) raised concerns that the proposed risk evaluation of formaldehyde (50-00-0) does not sufficiently recognize the risk to human health by excluding activities from the scope of the risk evaluation. The commenter listed a variety of potential “non-TSCA” uses, but only mentioned formaldehyde in regard to cosmetic products and hair straightening products.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0047) noted that, in addition to uses of formaldehyde (50-00-0) identified for exclusion from risk evaluation in the draft scope document, the final scope document should “specifically exclude medical devices, drug-device combination products,

food contact articles, and their components. Like personal care products, medical devices and their components, drug-device combination components, and food contact/ food additives fall outside the jurisdiction of TSCA because they are subject to regulation by . . .FDA . . . under the [Federal Food, Drug, and Cosmetic Act (FFDCA), 21 U.S.C. § 321].”

Comment: A commenter (EPA-HQ-OPPT-2019-0131-0038, EPA-HQ-OPPT-2019-0131-0049) stated “EPA specifically addresses the conditions of use that are excluded from scope, including uses such as food additives, cosmetics, drugs, and pesticides. However, EPA notes that, in some cases, manufacturing, processing, and industrial uses of these products are covered by TSCA and will be considered a condition of use. EPA should reach out to these impacted industries not typically regulated under TSCA, and ensure it coordinates with the appropriate regulatory authorities regarding that scope of risk evaluations that impact industries regulated by those agencies.”

Response: TSCA section 3(2) defines “chemical substance” to exclude certain uses/products, including any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq. (1996)) when manufactured, processed, or distributed in commerce for use as a pesticide, and any food, food additive, drug, cosmetic, or device (as defined in Section 201 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. Activities and releases associated with such uses/products are therefore not “conditions of use” (defined in TSCA section 3(4) to refer to circumstances associated with a “chemical substance”) and EPA does not plan to evaluate them during risk evaluation. Personal care products that meet the definition of cosmetic or drug would fall under this exclusion.

Comment: A commenter (EPA-HQ-OPPT-2018-0458-0033) agreed with the Agency’s proposed exclusion of nail polish and flea and tick collars from the Conditions of Use because the products are regulated by laws other than TSCA. Another commenter (EPA-HQ-OPPT-2019-0131-0033) noted that TPP (115-86-6) is found in many cosmetology products used for nail care and raised concerns that EPA proposes to exclude from the scope of the Risk Evaluation occupational exposures that may affect manicurists or other cosmetologists. The commenter argued that a comprehensive assessment of population risks should include such occupational pathways.

Response: EPA is excluding nail polish and flea and tick collars from the scope of the risk evaluation of TPP (115-86-6). Nail polish is a cosmetic and is covered by the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, and flea and tick collars are pesticides covered by the Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. § 136 et seq., so they are excluded from the definition of “chemical substance” in TSCA section 3(2)(B)(vi). Activities and releases associated with the use of such pesticides and nail polish are therefore not a “conditions of use” (defined as circumstances associated with “a chemical substance,” TSCA section 3(4)). Therefore, the use of TPP in nail polish and in flea and tick collars are outside the scope of the risk evaluation.

Comment: Two commenters (EPA-HQ-OPPT-2018-0433-0032 and EPA-HQ-OPPT-2018-0433-0031) submitted information about how certain FDA-sanctioned applications are specifically excluded from the scope of this risk evaluation, but it does not include medical devices and “as an indirect additive in food contact applications.” One commenter (EPA-HQ-OPPT-2018-0433-0032) asked for clarification on this matter. Another commenter (EPA-HQ-OPPT-2018-0433-0031) requests EPA add these two uses to the exclusion list.

Response: EPA appreciates the commenter bringing this to the Agency's attention. FDA resources show that di-ethylhexyl phthalate (117-81-7) is still used occasionally in both medical devices and indirect food contact (<https://www.govinfo.gov/app/details/CFR-2019-title21-vol3/CFR-2019-title21-vol3-sec177-1200/summary>). EPA will be adding these uses to the list of uses excluded from this risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028) stated "EPA has correctly noted that its risk evaluation cannot extend to uses of personal care products containing HHCB because these products are 'cosmetics' subject to regulation under the Federal Food, Drug, and Cosmetic Act, and so, are not 'chemical substances.'" and "Thus, the exclusion of "cosmetics" under TSCA should extend to exclude from the scope of this risk evaluation, the use of HHCB as an ingredient in manufacturing a cosmetic."

Response: As stated in the draft scope document, EPA determined that HHCB use in personal care products, including soaps, meets the definition of cosmetic in Section 201 of the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 321, and are therefore excluded from the definition of "chemical substance" in TSCA section 3(2)(B)(vi). Such personal care products use are therefore not considered "conditions of use" (defined as circumstances associated with "a chemical substance," TSCA section 3(4)) and will not be evaluated during risk evaluation.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0033) notes that the registration of ethylene dibromide (106-93-4) as a pesticide under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), 7 U.S.C. § 136 et seq. (1996), was canceled more than 30 years ago, because of concerns about toxicity to workers and bystanders. The commenter encourages EPA to mention this history in the Risk Evaluation for ethylene dibromide, and that EPA should urge that ethylene dibromide should never again be registered for use as a fumigant pesticide.

Response: EPA appreciates the comment and has already referenced the former pesticidal use for ethylene dibromide (106-93-4) in the Appendix D "Regulatory History" of the Scope of the Risk Evaluation. Since pesticidal use is excluded from the definition of "chemical substance" under TSCA section 3(2)(B)(ii), it is not a TSCA condition of use and will not be evaluated in the ethylene dibromide risk evaluation.

*Comment: A commenter (EPA-HQ-OPPT-2019-0131-0033) voiced concern that the proposed scope of the *p*-dichlorobenzene (106-46-7) Risk Evaluation would exclude such uses as mothballs, deodorizers and toilet care products. The commenter understands some of these uses fall under FIFRA, but nonetheless argues that "the assessment of downstream risks, including risks that might affect publicly owned treatment works (POTWs) and risks to the aquatic environment should be part of this risk evaluation." The commenter underscores the action by "many states" to ban the use of *p*-dichlorobenzene in consumer products because of concerns about the environmental fate of *p*-dichlorobenzene.*

*Response: EPA appreciates the commenter's detailed input. EPA plans to assess the TSCA uses of *p*-dichlorobenzene (106-46-7) in deodorizer and toilet care products as indicated in Table 2-2 of the draft scope document. The final scope document includes uses of the deodorizer and toilet care products and includes downstream conditions of use (disposal) of the deodorizer and toilet care products. EPA plans to evaluate risks to aquatic life from releases associated with the use of deodorizers and toilet care products. The use of *p*-dichlorobenzene as a conventional chemical insecticide as a moth repellent is excluded from the definition of "chemical substance" pursuant to TSCA section 3(2)(B)(ii) (providing*

that the term “chemical substance” does not include “any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act [7 U.S.C. § 136 et seq.]) when manufactured, processed, or distributed in commerce for use as a pesticide”). Activities and releases associated with such pesticidal uses are therefore not “conditions of use” (defined in TSCA section 3(4) to refer to circumstances associated with a “chemical substance”) and EPA does not plan to evaluate them during risk evaluation. EPA’s Office of Pesticide Programs (OPP) periodically conducts a Human Health Risk Assessment in support of a registration review for pesticides including p-dichlorobenzene. OPP released its most recent draft risk assessment for p-dichlorobenzene on November 30, 2018, and the Draft Human Health Risk Assessment is found in the Docket (EPA-HQ-OPP-2016-0117). EPA will consider the Draft Human Health Risk Assessment as reasonably available information when conducting the Risk Evaluation.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0047) stated that the polymers they manufacture using formaldehyde (50-00-0) are used in medical devices, drug device combination products, food contact articles, and therefore should be excluded from the scope of the risk evaluation for formaldehyde because they are regulated under FIFRA and FFDCa.

Response: EPA appreciates the comment and agrees that TSCA’s definition of “chemical substance” excludes pesticides (under FIFRA) or food, food additives, drugs, cosmetics, or devices (under FFDCa) when manufactured, processed, or distributed in commerce for such use. Thus, EPA considers formaldehyde (50-00-0), either on its own or as part of a mixture or article, to be in scope until the point it becomes manufactured, processed, or distributed in commerce for an excluded use (e.g., as a medical device or food additive). EPA believes that the processing, distribution, and use of formaldehyde as part of the commenter’s polymer product would be subject to TSCA when intended for use in various commercial and consumer applications that are not FIFRA- or FFDCa-excluded uses.

Federal Preemption

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0047) urged EPA to “affirmatively state that conditions of use and routes of exposure considered beyond scope do not pose an unreasonable risk” and “clearly articulate a ‘no unreasonable risk’ determination for any condition of use not included in the scope documents.” The same commenter also requested that EPA add language to the scope documents affirming that conditions of use that EPA has determined are out of scope and do not need further evaluation are considered to preempt further state actions. The same commenter asked EPA to clarify how regulation of “conditions of use” covered by other EPA statutes is considered adequate to meet a finding of “no unreasonable risk” and preclude state preemption of EPA’s findings and to articulate the legal argument as to how other conditions of use that EPA has determined are adequately regulated by other federal agencies cannot be preempted by states.

Comment: Another commenter (EPA-HQ-OPPT-2018-0458-0033, EPA-HQ-OPPT-2018-0462-0038) encouraged EPA to have a process in place to notify state regulatory bodies and state legislatures of the pause preemption once the final scope document is published.

Response: EPA appreciates comments on preemption from potentially affected persons and understands the interest in preemption for TSCA uses. EPA disagrees with the commenter that a decision to exclude a condition of use or exposure pathway from the scope of a TSCA risk evaluation would have any preemptive effect over state action. Under TSCA section 18(a)(1)(B) and (c)(3), federal preemption over certain State actions applies to chemical substances for which a determination of ‘no unreasonable risk’ has been made pursuant to TSCA section 6(i)(1) or for which a final risk management rule is

promulgated pursuant to TSCA section 6(a) and does not extend to those hazards, exposures, risks, and uses or conditions of use not included in that final determination or rule. TSCA section 18(b) and (c)(2) also provide for temporary federal preemption (pause preemption) for those hazards, exposures, risks, and uses or conditions of use of a chemical substance included in the scope of a risk evaluation, beginning on the date on which EPA defines the scope of the risk evaluation and ending on the deadline for completion of the risk evaluation or the date EPA publishes the risk evaluation, whichever is earlier. Pursuant to TSCA section 18(c)(3), if uses or exposure pathways are not “included in any final action the Administrator takes pursuant to section [6(a) or 6(i)(1)],” (e.g., because EPA determines the use or exposure pathway to be outside of the scope of the risk evaluation (such as uses regulated by EPA or other Federal agencies under other federal laws)), then TSCA permanent preemption does not apply.

In regard to having a process in place to notify state regulatory bodies and state legislatures, thank you for raising this issue. The Federal Register Notice announcing the final scope documents is envisioned as the mechanism for giving notice to states and interested stakeholders about EPA’s approach for evaluating a chemical and the conditions of use that fall under pause preemption.

Submitted Data and Information

Hazard and Exposure Potential

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0025, EPA-HQ-OPPT-2018-0433-0037) provided a conceptual model for environmental releases and wastes and examples of exposures linked to waste handling, treatment, and disposal that affect tribes.

Comment: Another commenter (EPA-HQ-OPPT-2018-0458-0033, EPA-HQ-OPPT-2018-0462-0038) stated “consideration of the mode of action (MOA) data is necessary when evaluating the human relevance of carcinogenicity findings from animal studies. A study using Toxicity Forecaster (ToxCast) and Toxicology in the 21st Century (Tox21) data examined the use of high-throughput in vitro screening (HTS) to predict potential carcinogenic hazards and risks to humans. It found that conclusions cannot be made from in vitro studies alone using assays currently mapped to characteristics of carcinogens that one or multiple molecular mechanisms are likely to be operative in inducing cancer or creating a cancer hazard. Moreover, the findings demonstrate the need for robust procedures to organize, evaluate, and integrate the relevance and reliability of mechanistic datasets with animal toxicity, epidemiological investigations, and knowledge of exposure and dosimetry to evaluate potential carcinogenic hazards and risks to humans.”

Response: EPA appreciates the information submitted. EPA will consider such information to the extent it is relevant to the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that are part of each risk evaluation. In applicable situations, EPA has described in each final scope document the specific ways in which it is modifying elements or including new information based on such public comments.

Comment: In comments related to 1,3-butadiene, one commenter (EPA-HQ-OPPT-2018-0451-0037) provided a list of work practices at U.S. tire manufacturing facilities.

Response: EPA appreciates this information and invites the submission of any additional information supporting the various measures taken by the tire industry to manage material releases. It would also be useful to better understand methods by which 1,3-butadiene leaches out of commercial/consumer products, the frequency or likelihood of such releases and the amount.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) described the use of 1,3-butadiene in the manufacture of synthetic polymers that are used in the manufacture of tires. The commenter stated “the amount of 1,3-butadiene that may theoretically be emitted from [butadiene rubber]and [styrene butadiene rubber] in a finished tire is an order of magnitude, or more, lower than the 50 ppb residual 1,3-butadiene estimated to be in [styrene butadiene rubber] and [butadiene rubber]. Therefore, 1,3-butadiene monomer comprises an insignificant mass in the overall composition of a finished tire. 1,3-butadiene cannot be created from the use of synthetic rubber in the manufacture of a tire because once polymerization has occurred it is nearly impossible to break the polymer chain back into individual units of 1,3-butadiene.”

Response: Thank you for providing this information. Understanding the amount or weight fraction of 1,3-Butadiene monomer that is available for potential exposure is very important. This information is a key parameter used in our Consumer Exposure Model. EPA recommends the submission of any potentially relevant weight fraction data commenters are able to provide.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) described the process by which 1,3-butadiene might accumulate in biosolids and stated “biosolids can only accumulate 1,3-butadiene if they have adhered to soil particles. There have been several studies of the chemicals in biosolids. As noted by the ATSDR Toxicological Profile 1,3-butadiene is not expected to attach easily to solids. Based on existing data, it is appropriate to determine that there is virtually no risk from this pathway.”

Response: Given preliminary findings for physical-chemical property and fate data, EPA believes it is unlikely that 1,3-butadiene will sorb to biosolids due to its volatility (vapor pressure and Henry’s Law Constant), water solubility and unlikely sorption to sludge (Log K_{oc}). EPA does not plan to evaluate this pathway for 1,3-butadiene.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) recommended that EPA not use the 2004 ESD on Additives in the Rubber Industry, to evaluate releases of 1,3-butadiene from use of synthetic rubber in tire manufacturing and stated “[t]he OECD emissions release document for additives in the rubber industry contains emission release equations that are established for materials that are added to the rubber matrix, not for residual materials in synthetic rubber. Therefore, the use of these emission release equations is not appropriate for use in the 1,3-butadiene risk evaluation.”

Response: Thank you for providing your comment. EPA will consider this information on the use of 2004 ESDs on Additives in Rubber Industry during the risk evaluation phase.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) offered to share information with EPA regarding the use of synthetic polymers manufactured with 1,3-butadiene in tire retread manufacturing facilities and in tire retreading facilities, as well as questions about synthetic rubber manufacturing facilities owned and operated by members of their organization.

Response: Thank you for providing your comment. EPA would appreciate submission of data on operations, releases and occupational exposures at these facilities. Such data would be reviewed as part of the Agency’s systematic review process.

Comment: One commenter (EPA-HQ-OPPT-2018-0503-0030, EPA-HQ-OPPT-2018-0438-0039; EPA-HQ-OPPT-2018-0433-0030) submitted lists of: toxicology and ecotoxicology studies for dibutyl

phthalate; ecotoxicity and environmental fate studies for formaldehyde; and a list of toxicology and ecotoxicology studies for DEHP.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0038) provided extensive appendices that included information related to 1,3-butadiene, including lists of human and animal hazard studies, a study on reproductive and developmental toxicity, and a list of studies related to synthetic rubber.

Comment: One commenter (EPA-HQ-OPPT-2018-0446-0034) referred EPA OPPT to EPA's OPP risk assessment for *p*-dichlorobenzene, stating that it represents the best available science for *p*-dichlorobenzene and human health hazard and that it "will inform the hazard identification, dose-response assessment, mode of action (MOA), and points of departure (POD) approaches." The commenter also directed EPA to the ECHA evaluation of *p*-dichlorobenzene. The 2013 Committee for Risk Assessment (RAC) and Committee for Socio-economic Analysis (SEAC)'s background document details relevant human health hazard regarding a threshold for carcinogenic effects, stating that both the 2018 OPP evaluation and the 2013 ECHA evaluation similarly conclude that there is a threshold for carcinogenic effects.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0052) provided extensive appendices that included information related to phthalates and plastics, including ecotoxicity associated with microplastics, the effect of plastics and microplastics on health and the environment, plastics found in wastewater discharges, and the presence of microplastics in drinking water.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028), in regard to HHCB, supported the Agency's consideration of the effects of engineering controls and PPE when evaluating risks to workers and offered to assemble a description of typical engineering controls and PPE currently in use.

Comment: A commenter (EPA-HQ-OPPT-2018-0462-0031) offered to work with EPA TSCA to ensure understanding and to provide the best data and information regarding risk to the potentially exposed populations for TBBPA that will be considered in the risk evaluation.

Comment: Two commenters (EPA-HQ-OPPT-2018-0465-0030, EPA-HQ-OPPT-2018-0465-0036) provided information on trans-1,2-dichloroethylene, describing it as a "safe alternative to water based cleaners," and noting that the "semiconductor industry uses trans-1,2-dichloroethylene with extensive controls for specialized uses to meet stringent performance requirements Known alternatives pose significant increased risk to human health and the environment."

Response: EPA appreciates the suggestions on information sources that EPA should use in the risk evaluation process.

Comment: A commenter (EPA-HQ-OPPT-2018-0458-0027) provided test data on TPP.

Response: EPA thanks the commenter for the information. EPA will evaluate the test data during the risk evaluation. EPA welcomes and will consider new information submitted during the risk evaluation phase.

Comment: A commenter (EPA-HQ-OPPT-2018-0433-033) noted that the scope document states that "dimerization of butyraldehyde can also be used as a means of di-ethylhexyl phthalate manufacture (Cadogan & Howick 2001)." The commenter stated "2-Ethylhexyl alcohol, the alcohol used to make

DEHP via esterification of phthalic anhydride, is made by aldol condensation of n-butyraldehyde followed by hydrogenation. One might understand the aldol condensation as ‘dimerization,’ but DEHP itself if not made by any route that could be considered dimerization.”

Response: Thank you for this information. EPA will remove the incorrect statement.

Surrogate Chemical Substances

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0037) cautioned EPA on the use of styrene as a surrogate for 1,3-butadiene because the amount of 1,3-butadiene and styrene residuals will be different if these two different chemicals are used for a different purpose and in a different part of the production process. The commenter stated “Nothing in the scope indicates that these two chemicals should be the same residual amounts. The reactivity of 1,3-butadiene is greater than the styrene monomer, thus, their behavior and relative prevalence in different parts of the tire making process will be different. Thus, one cannot estimate 1,3-butadiene from styrene levels without empirical evidence, and there is none. Accordingly, it is not scientifically sound to use styrene as an indicator of 1,3-butadiene.”

Response: EPA will consider this information provided on the use of styrene as a surrogate during the risk evaluation. For the final scope document, EPA has removed styrene as an example surrogate.

*Comment: One commenter (EPA-HQ-OPPT-2018-0446-0034) asserted the need for EPA to use actual *p*-dichlorobenzene data to evaluate and regulate this chemical, stating “EPA should first demonstrate that *p*-dichlorobenzene data is insufficient before it considers surrogate chemicals. Should the EPA identify the need to use surrogate chemicals, the *p*-DCB Consortium would welcome the opportunity to review and comment on the appropriateness of the selected surrogate chemicals.*

*Response: EPA appreciates the commenters willingness to aid the Agency in choosing surrogate chemicals to evaluate the potential risk of *p*-dichlorobenzene. However, as stated previously, as part of the risk evaluation process, EPA may identify additional data through systematic review and will evaluate all reasonably available data and information. EPA prefers to review *p*-dichlorobenzene data when it is reasonably available and when it meets the criteria of EPA’s systematic review process. When data are not reasonably available, do not meet the Agency’s systematic review criteria, and/or there are data needs that limit the EPA’s ability to thoroughly evaluate the chemical, EPA plans to look at surrogate data to try to estimate the potential risk of that chemical.*

Production Volume

Comment: One commenter (EPA-HQ-OPPT-2018-0433-0031) submitted production volume data for DEHP.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028) offered to make available to EPA, information regarding the concentrations of HHCb in finished commercial and consumer products for a variety of product categories.

Comment: Two commenters (EPA-HQ-OPPT-2018-0488-0035, EPA-HQ-OPPT-2018-0488-0034) submitted nearly identical comments, with (EPA-HQ-OPPT-2018-0488-0034) stating that the “summary in this Use Report for Ethylene Dibromide (Use Report) correctly points out that unleaded avgas, UL94, is the only commercially available unleaded aviation gasoline in the US, and approximately 65% of piston (small) aircraft in the US are compatible with this type of fuel. The summary in the Use Report failed to mention that not only do the remaining 35% of the fleet consume the majority of the leaded fuel, but it is this segment of the piston aircraft fleet that is most critical in regards to serving the needs

of the transportation infrastructure of the country. This includes the transportation of essential workers and supplies to the more than 5,000 public use airports across the country and in remote areas of Alaska. In consideration of the demonstrated impact general aviation has to society and the economy, it is imperative these uses are included in the final Scope of the Risk Evaluation.” Other commenters (EPA-HQ-OPPT-2018-0488-0029, EPA-HQ-OPPT-2018-0488-0028) suggested there is no need to prioritize further risk evaluations, undertake further testing, or develop further regulatory action for Ethylene Dibromide for a variety of reasons, including “[q]uantities of EDB used in aviation fuel are far less than projected in the Draft Scope of the Risk Evaluation for Ethylene Dibromide proposal document . . . [t]here has been a 60 percent reduction in the TEL and EDB content of aviation gasoline in recent decades that, when combined with a 60 percent decrease in the volume of fuel consumption over that same timeframe, has resulted in a greater than 80 percent overall reduction in EDB use in aviation gasoline . . . EDB is not manufactured in the U.S. for aviation use and is only imported as part of the finished octane enhancing TEL-B additive package from a single source global supplier . . . [t]here is no consumer or fuel distribution level contact with the TEL-B additive containing EDB in other than its highly diluted form in finished aviation gasoline; approximately 0.07% EDB by weight . . . [and t]here is minimal risk to soil, air, and water sources because EDB is shipped and blended with bulk fuel components in sealed containers and blending systems at a very select few industrial facilities.”

Response: EPA appreciates the suggestions on information sources that EPA should use in the risk evaluation process. EPA welcomes and will consider new information submitted during the risk evaluation phase.

Other Information

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0036) submitted information on market outlook and regional production on structural panels and engineered wood products.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0047) submitted background information on a polymer produced from formaldehyde-derived monomers. The same commenter provided informational materials and correspondence with EPA related to formaldehyde in medical devices, drug-device combination components, and food contact materials/food additives.

Comment: One commenter (EPA-HQ-OPPT-2018-0451-0027) provided a series of slides describing synthetic rubber production processes and residual presence of 1,3-butadiene.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0035) requested that previously submitted June 2019 comments regarding specific information on ongoing automotive uses of the 20 High-Priority Substances in articles and nondimensional applications included by reference for consideration as conditions of use.

Comment: One commenter (EPA-HQ-OPPT-2018-0504-0043) stated “[dicyclohexyl phthalate] has had a technical dossier submitted to the . . . ECHA under Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the . . . REACH. The technical dossier contains either data or justified waivers for all endpoints relevant for an Annex IX registration.” The same commenter requested that EPA await the results of the “OECD 234 – Fish Sexual Development Test” study as part of the “2017 Community Rolling Action Plan (CoRAP) under the REACH Regulation” to better inform the risk evaluation process.

Response: EPA appreciates the suggestions on information sources that EPA should use in the risk evaluation process.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028) noted the formation of an HHCB Task Force that will be conducting a systematic, weight of evidence review of the literature regarding HHCB's bioaccumulation potential and offered to submit a white paper on this topic to EPA before the end of the year.

Response: EPA looks forward to reviewing the white paper and will incorporate it into our evaluation, as appropriate.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028) recommended that EPA consider data regarding wastewater, surface water and sediment concentrations, available from the U.S. Geological Survey (USGS)'s National Water Information System (NWIS) in regard to ambient environmental concentrations.

Response: Thank you for the comment. In its assessment of HHCB, EPA will consider the most up-to-date USGS NWIS Data.

Comment: One commenter (EPA-HQ-OPPT-2018-0430-0028) provided a list of privately-funded studies of HHCB's physical/chemical properties, environmental fate, ecotoxicity, and potential human health effects. The commenter stated "The citations for studies owned by entities other than [the Research Institute for Fragrance Materials (RIFM)] have been redacted to protect the owners' proprietary interests in those studies. It is [the commenters'] intent to provide EPA with full study reports for all studies that are owned by either RIFM or International Flavors & Fragrances Inc. (IFF), assuming agreement can be reached with EPA regarding permissible redactions that will protect the proprietary value of the reports owned by IFF."

Response: EPA looks forward to reviewing any submitted HHCB studies and integrating the results into the risk evaluation as appropriate; however, EPA cannot guarantee any CBI protections in light of TSCA section 14(b)(2) and 40 CFR 2.306(b). The Agency considers these studies to be within TSCA section 8(d) authority (i.e., contain "potential human health effects" information, suggesting they meet the statutory definition of "health and safety study" and can be required to be submitted by "any person who has possession of" such studies), and is considering exercising that authority. Note that if the company provides the studies in advance of promulgation of a rule under TSCA section 8(d), the Agency will treat the studies as having been submitted pursuant to the authority of TSCA section 8(d), and therefore subject to the disclosure provisions in TSCA section 14(b)(2), as applicable.

Comment: One commenter (EPA-HQ-OPPT-2018-0421-0022) provided information related to releases and transfers of High-Priority Substances in communities in Louisiana and Texas.

Response: EPA appreciates the information submitted. EPA will consider such information to the extent it is relevant to the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations as part of each risk evaluation. As necessary, EPA is describing in each final scope document the specific ways in which it is modifying elements or including new information based on such public comments.

Comment: A commenter (EPA-HQ-OPPT-2018-0428-0022, EPA-HQ-OPPT-2018-0438-0030, EPA-HQ-OPPT-2018-0462-0026) submitted an initial response in CDX on behalf of Hexion Holdings, LLC, which was identified on the preliminary list of responsible parties but has ceased manufacture. Hexion Holdings, LLC was dissolved and replaced by Hexion Holdings Corporation.

Response: EPA thanks the commenter for their information, this comment pertains to the preliminary manufacture fees list. While the comment does not pertain to the draft scope documents, EPA will ensure that the final manufacturer fee list reflects this updated information.

Comments Related to Risk Management

Exemption for Articles and Replacement Parts

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0035) recommended that EPA “reconsider its past policy and practices regarding articles and adopt a policy that exempts articles from inclusion in conditions of use and regulation under TSCA §6 unless EPA has specific data that indicates an exposure of concern and a risk associated with the article itself” and issue guidance for comment on how the Agency interprets the terms “intended, known, or reasonably foreseen.” The commenter asserted that such approach “would significantly lessen the burden on those who import articles by ensuring that they would only need to expend resources in review of TSCA risk evaluations and regulatory actions that have identified a specific risk as directed by TSCA §6(c)(2)(E). At the same time, this approach would allow EPA to address risk from any individual article.” The same commenter recommended “a presumptive exemption for replacement parts unless EPA has data that indicates that a specific replacement part ‘contribute(s) significantly to the risk, identified in a risk evaluation’” and that such an exemption be addressed in a scope document “so that companies do not need to expend time and resources to identify chemicals in what can best be termed a ‘legacy’ use and excluded from scope.” The commenter also requested that EPA develop and publish for comment its proposed approach to assessing replacement parts based on specific requirements in TSCA sections (3)(B)(4) and 6(c)(2) (D).

Response: The Agency appreciates this feedback from potentially affected persons. During the risk evaluation process, EPA determines whether or not the chemical substance presents an unreasonable risk to health or the environment under the conditions of use. If unreasonable risk is identified, then the Agency will initiate any necessary risk management action to address such risk.

EPA notes that TSCA section 6(c)(2)(D) (replacement parts) and (E) (articles) applies to risk management. If unreasonable risk is identified during the risk evaluation process, then any regulatory action will consider articles and replacement parts. As such, EPA will consider the evaluation of articles, components, and replacement parts as necessary during the risk evaluations of High-Priority Substances, and, if needed, will follow TSCA section 6(c)(2)(D)-(E) during any risk management phase.

Note that, as a result of the Ninth Circuit Court of Appeals’ decision in *Safer Chemicals, Healthy Families v. U.S. EPA*, 943 F.3d 397, 425 (9th Cir. 2019), EPA is no longer excluding legacy uses (i.e., circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution) or associated disposal (i.e., ongoing disposals from legacy uses) from the definition of “conditions of use.” Rather, when these activities are intended, known, or reasonably foreseen, these activities are considered uses and disposal, respectively, within the definition of “conditions of use.”

De Minimis Threshold for Chemicals in Articles and Mixtures and Exemption for Research and Development

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0035) recommended that EPA establish a *de minimis* threshold for chemicals in articles and mixtures based on a “reasonable potential for exposure” and suggested a standard default *de minimis* of 0.1 percent. The commenter stated that such a threshold “would allow EPA to focus on major sources and would allow for more effective use of the automotive industry’s long-term investment in its internal [International Material Data System] system.”

Comment: Another commenter (EPA-HQ-OPPT-2018-0444-0026, EPA-HQ-OPPT-2018-0446-0028) identified two products they manufacture that contain *o*-dichlorobenzene and *p*-dichlorobenzene and provided information on the recommended use of these products as fuel additives and lubricants for engines and tools, the *de minimis* volumes of *o*-dichlorobenzene present in the formulas, and the Tier 1 Testing performed on one product to be registered under EPA as a fuel additive. The commenter suggests *p*-dichlorobenzene may be a contaminant of *o*-dichlorobenzene but indicated they have no test results that show the presence of *p*-dichlorobenzene in the products. The commenter believes that the products “pose no risk to either health or the environment” and “should be excused from participation in further EPA risk evaluation activities and potential additional regulation.”

Comment: A commenter (EPA-HQ-OPPT-2018-0444-0028) suggested that EPA drop consideration of commercial and consumer uses in the risk evaluation that have residual levels (less than 1%) of *o*-dichlorobenzene, as potential exposure to the chemical substance is low.

Comment: A commenter (EPA-HQ-OPPT-2018-0451-0038) provides information for many conditions of use. For “Processing aids, not otherwise listed in: Petrochemical manufacturing,” the commenter states that to the best of their knowledge, the chemical is not added or used as a processing aid within any petrochemical manufacturing operations. They state that following the distillation/refinery process, 1,3-butadiene is found in concentrations below 0.5% in liquefied petroleum gas and that no 1,3-butadiene is found in gasoline or other liquid fuels above 100 ppm. The commenter also states that there appear to be only residual amounts of 1,3-butadiene in the following conditions of use scenarios that involve reactants and monomers: “processing in adhesive manufacturing, paints and coatings manufacturing, petroleum lubricating oil and grease manufacturing, and all other chemical product and preparation manufacturing,” “processing as polymer in rubber product manufacturing,” “industrial use in adhesives and sealants, and processing aids, specific to petroleum production,” “commercial use of plastic and rubber products not covered elsewhere, automotive care products, lubricants and lubricant additives, paints and coatings, and adhesives and sealants,” and “consumer use of plastic and rubber products not covered elsewhere.”

Comment: A commenter (EPA-HQ-OPPT-2018-0438-0040) stated “Funeral directors use a small amount of formaldehyde in each embalming and each embalming is of a short duration A typical embalming lasts from 45 to 90 minutes with an average time of one hour Funeral directors do not embalm daily and with the increase in the cremation rate, funeral directors may conduct embalming only several times a week Funeral service accounts for only approximately one percent of total formaldehyde usage each year in the United States [And t]he use of formaldehyde in embalming is far less than the other uses EPA has identified for risk assessment.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0039, EPA-HQ-OPPT-2019-0131-0050) noted the “benefit of evaluating *de minimis* amounts in a condition of use to preserve comprehensiveness of EPA’s risk evaluations and to establish a national-level determination on *de minimis* values, pre-empting state action, where EPA has adequate reasonably available information and does not rely on overly

conservative assumptions regarding exposure from a *de minimis* use.” The commenter offered to assist EPA in providing relevant information to evaluate *de minimis* amounts.

Comment: One commenter (EPA-HQ-OPPT-2018-0438-0053) requested that the Agency revise and correct the draft scoping document to note that: “(a) formaldehyde is present only in minute (trace) quantities in a limited number of formulations used in enclosed processes in semiconductor manufacturing; (b) no direct worker exposures to formaldehyde occurs in any semiconductor operations involving its use; (c) formaldehyde does not remain present in semiconductor wafers produced under these conditions of use; and (d) there are no commercial user or consumer exposures to formaldehyde in products produced in the semiconductor manufacturing sector.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0035) requested that EPA consider an exemption that would relieve research and development programs from consideration during the scoping process similar to EPA’s TSCA section 5(h)(3) exemption. The commenter suggested that the exemption could be narrowly crafted to ensure that activities were limited to “the analysis of the chemical or physical characteristics, the performance, or the production characteristics of a chemical substance, a mixture containing the substance, or an article ”and focus on small quantities solely for the purposes of scientific experimentation or analysis, or chemical research for the development of a product. The commenter asserted that an exemption from conditions of use as defined in TSCA (3)(B)(4) “would allow our R&D programs to continue their essential work without the time and financial burden imposed by regulation.”

Response: As discussed in the preamble to the final rule (82 Fed. Reg. 33726, 33728-30, July 20, 2017), EPA has adopted an approach by which it will determine each chemical’s conditions of use on a case-by-case basis. EPA believes that to effectively conduct a risk evaluation on a chemical substance it must identify the uses of each chemical. During the scoping phase of a risk evaluation, EPA may determine that there are appropriate regulatory safeguards in place for a particular use or that a particular use would present only *de minimis* exposures, and that these uses can be excluded from assessment as part of the risk evaluation. But because this is necessarily a case-by-case approach, EPA does not think including a blanket provision excluding particular uses from risk evaluation is appropriate.

*EPA acknowledges that there will likely be uses that present little to no exposure. However, without some kind of evaluation that is unique to the particular chemical’s hazard and exposure scenarios, EPA cannot determine whether there is no unreasonable risk for the condition of use. Therefore, EPA maintains that adherence to a risk-based approach does not support a blanket exclusion, including *de minimis* threshold, based on a reasonable potential for exposure or *de minimis* use.*

Similarly, EPA has not adopted a categorical exclusion from the statutory definition of “conditions of use” for research and development activities.

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0044) stated that since promulgation of the MACT Standard in 1999, the industry has voluntarily undertaken a major effort to discontinue phenol formaldehyde (PF) binders and that each manufacturer has developed its own substitute for PF binders, which had been used by the industry for 50-plus years. The non-phenol formaldehyde (non-PF) substitute binders do not contain hazardous air pollutants (HAPs) in quantities above those required to be reported as constituents on Safety Data Sheets (SDSs). Further, they state EPA has confirmed that those fiber glass insulation manufacturing plants that made the switch to a non-PF binder are not subject to the Fiber Glass MACT Standard and that the major HAP emitted during the manufacturing of wool

fiber glass – formaldehyde – has been virtually eliminated from all the raw materials used in those facilities that have switched to non-PF binders.

Response: Ambient air releases of formaldehyde from industrial and commercial stationary sources are covered under the jurisdiction of other EPA statutes (specifically the CAA and RCRA) as described in section 2.6.3. This can be seen in Section 2.6.3.1, 2.6.3.4, and Figure 2.11 in the scope document. Formaldehyde is a listed hazardous air pollutant under Section 112 of the Clean Air Act.

Environmental Justice

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0036, EPA-HQ-OPPT-2019-0131-0047) urged EPA to ensure that environmental justice is appropriately considered, analyzed and addressed in the risk evaluation process. The commenter stated “EPA does not appear to have undertaken any outreach oriented towards ensuring the meaningful involvement of environmental justice communities in the scoping process” pursuant to Executive Order 12898 and “EPA must address environmental justice both by incorporating an analysis into the scopes of these 20 risk evaluations and ensuring meaningful involvement of environmental justice communities as it moves forward.”

Comment: Another commenter (EPA-HQ-OPPT-2018-0421-0025, EPA-HQ-OPPT-2018-0433-0037) echoed “[t]ribes are a minority and low-income population whose lifeways place them at higher exposure potential to chemicals in the natural environment so that EPA must include exposure scenarios representative of tribal lifeways in its TSCA risk assessment process.” The same commenter referenced the American Indian Religious Freedom Act of 1978 (AIRFA) (42 U.S.C. § 1996.) and stated “[w]hen EPA presumes that environmental and other federal statutes protect a population from chemical release exposures, it must consider tribes practicing ceremonial and traditional activities, which are a protected basic American right. We note that EPA’s TSCA risk assessment process includes a risk management stage following the risk evaluation stage. EPA cannot adequately manage chemical risks to tribal populations without including tribal practices in the risk evaluation. Without addressing risks to tribal practices in the evaluation stage, EPA risks violating AIRFA.”

Comment: One commenter (EPA-HQ-OPPT-2019-0131-0031, EPA-HQ-OPPT-2019-0131-0052) recommended that EPA include in the risk evaluations “vulnerable communities of color” and stated “[m]any petrochemical facilities are in minority and low-income communities already suffering from high pollution levels; incidences of cancer, illness, and other health and environmental impacts; depreciating property values; and declining public services due to existing industrial facilities, terminals, and pipelines clustered in the same areas. Additionally, about 80 percent of the incinerators are located in low-income or communities of color.”

Response: TSCA requires EPA to consider potentially exposed and susceptible subpopulations as part of the risk evaluation process, which the Agency views as carrying out the spirit of Executive Order 12898. For example, human health and environmental hazards, as well as environmental and human exposures, including PEES, were considered during the development of the draft scope documents for all High-Priority Substances. Furthermore, “potentially exposed or susceptible subpopulations” may include subpopulations with unique exposure circumstances or people living in geographic areas near high-volume chemical facilities, which will be considered as part of the risk evaluation process for each of the High-Priority Substances. Finally, if unreasonable risk is identified, then the Agency will initiate risk management actions to address such risks, which will include addressing unique exposure circumstances and environmental justice concerns, as appropriate.

The Agency is committed to consultation and coordination with Tribes (see the EPA Policy on Consultation and Coordination with Indian Tribes available at <https://www.epa.gov/tribal/forms/consultation-and-coordination-tribes>).