(as of December 6, 2019)

# EPA's Responses to Public Comments Received on the "Initiation of Prioritization Under the Toxic Substances Control Act (TSCA)" and "Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA)"

In this document, EPA is responding to overarching, cross-cutting policy and process comments, as well as chemical-specific comments received during the two public comment periods regarding the announcement of candidates to initiate prioritization and the proposed designations for High-Priority Substances for risk evaluation.

For the candidate High-Priority Substances, comments were received in two phases: (1) a 90-day comment period following the initiation of the prioritization process for the 20 chemical substances identified as candidates for High-Priority Substance designation (84 FR 10491, March 21, 2019); and (2) a 90-day comment period following the proposal of the same 20 chemical substances identified as candidates for a High-Priority Substance designation (84 FR 44300, August 23, 2019). In both phases, interested persons were able to submit relevant information on the 20 chemical substances. EPA created one general docket to receive comments regarding the prioritization process and additional individual chemical dockets to receive chemical-specific information. From both comment periods and all 21 dockets, EPA received a total of 229 submissions; however, some commenters opted for one submission describing all their comments and submitted it to multiple dockets while other commenters chose to submit different comments to each chemical-specific docket. Therefore, EPA considered 106 of those submissions unique. In addition, one submission, which was submitted to all 21 dockets, is considered a mass mailing campaign since it was endorsed by 60 individuals. 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 52 different entities, including 11 from private citizens, 26 from potentially affected businesses or trade associations, 8 from environmental and public health advocacy groups and academia (some submissions were signed by more than one group), 6 from other organizations and 1 from a state government. Comments addressed the overall prioritization process (e.g., the collection and consideration of relevant information), the review process (e.g., the use of data and approaches for screening review), information specific to the candidate chemical substances (e.g., relevant studies, assessments and conditions of use), and topics beyond this prioritization process (e.g., scheduling future chemicals for prioritization, risk evaluation, risk management and concerns about risk evaluation fees). Two comments were on topics not related to prioritization. To the extent that comments from the first phase provided information on additional conditions of use for the candidate High-Priority Substances, those conditions of use were discussed in the proposed designation documents for each chemical substance. Other submitted information specific to High-Priority Substances (e.g., relevant studies and assessments) was considered when making the final priority designations and will be considered in subsequent phases of the chemical-specific risk evaluations.

## Overall Prioritization Process

Approach and Rationale

*Comment:* Several commenters requested that EPA clearly explain its approach to applying the statutory considerations and criteria of TSCA section 6(b)(1)(A) during the screening review of the candidate chemical substances, as well as its rationale for proposed priority designations (EPA-HQ-OPPT-2019-0131-0005, EPA-HQ-OPPT-2019-0131-0006, EPA-HQ-OPPT-2019-0131-0011).



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*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0006/EPA-HQ-OPPT-2019-0131-0018) requested an explanation of how EPA would address instances where new data indicated that "some Work Plan chemicals identified as high priority candidates might not satisfy the TSCA Section 6 prioritization screening criteria and/or definition of a high priority or even the TSCA Section 26 science standards." The commenter also requested clarification on how EPA ascertains whether the hazard potential information used to support the 2014 TSCA Work Plan is consistent with the scientific standards of TSCA section 26(h), inclusion of more detail of TSCA section 26(h) review in its proposed designation support documents, and indication of whether the Agency has updated an information source.

*Comment*: Another comment (EPA-HQ-OPPT-2019-0131-0013) stated that "EPA should establish risk-based screening process and criteria" and "should not decouple the hazard and exposure elements from the risk equation and transform them into independent considerations."

*Response: As required by Congress and codified in the "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act" Rule (40 CFR sections 702.1-702.17), there are two comment opportunities during the prioritization process, so that the public would have time to submit relevant information on the chemical substances considered for prioritization. EPA considered the information submitted as part of its proposed and final designations, in accordance with applicable statutory and regulatory requirements.*

*EPA considered several approaches and tools for identifying potential candidate chemicals for prioritization. These approaches were presented at a December 11, 2017 public meeting (EPA-HQ-OPPT-2017-0586* [ HYPERLINK "https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2017-0586" ]*), and there was general support for using the 2014 Work Plan chemicals as the starting point for identifying potential high-priority candidates. TSCA section 6(b)(2)(B) further requires that 50 percent of all ongoing risk evaluations be drawn from the 2014 TSCA Work Plan for Chemical Assessments. As presented during the meeting, selection of a chemical substance from the 2014 Work Plan as a candidate for High-Priority Substance designation does not constitute a finding of risk. These chemicals will be subject to the prioritization process for determination of high-priority designation. EPA recognizes that additional information may have been identified or developed for chemicals on the 2014 Work Plan since its issuance. As each chemical was considered for prioritization, EPA has identified and reviewed reasonably available information, including any new information and public comments, to ensure that information is consistent with the TSCA scientific standards.*

*For prioritization, EPA considered sources of information consistent with the scientific standards in TSCA section 26(h), including the sources listed in Appendices A and B of the 'TSCA Work Plan Chemicals Methods Document' (February 2012), as required by the 'Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act rule (40 CFR 702.9(b)).' EPA has used the most recent information from those sources.*

*EPA developed a proposed designation document for each candidate chemical substance to identify the information, analysis and basis used to support the proposed designation as a High-Priority Substance. These documents are available in the respective dockets of each chemical substance with a proposed designation as a High-Priority Substance. Also included in each document is an explanation of the approach used by EPA to conduct the review of the candidate chemical substances. Each document includes an overview of the requirements in TSCA section 6(b)(1)(A) and in the regulation addressing the "screening review criteria" and considerations for proposed priority designations (40 CFR 702.9). Those documents describe how EPA considered each of the applicable statutory and regulatory*

*requirements and criteria, including those related to the "conditions of use or significant changes in conditions of use" and "potentially exposed or susceptible subpopulations," to support the proposed designation.*

*TSCA section 6(b)(1)(A) requires EPA to determine whether a chemical may present unreasonable risk "because of a potential hazard and a potential route of exposure," indicating that hazard and exposure are separate considerations that together impact the risk-based priority designations.*

*EPA also clarifies that the prioritization process did not include an update of the 2014 Update to the TSCA Work Plan for Chemical Assessments.*

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0011) urged EPA to "accurately identify" relevant potentially exposed or susceptible subpopulations (PESS), including infants, children, pregnant women, workers, the elderly, and "people living in proximity to sources of contamination." The same commenter called for "ensur[ing] that environmental justice is appropriately considered, analyzed, and addressed in the prioritization process." Another commenter (EPA-HQ-OPPT-2019-0131-0016) indicated that "Tribes must be considered as a sensitive subpopulation under TSCA" given the "unique lifeways that place them at different risk due to multiple exposure pathways not experienced by the general population," such as diet, housing, worker safety protocols, untreated drinking water, daily and ceremonial steam baths, artisanal activities, subsistence activities, and recreational activities. The commenter cited a Scientific Advisory Committee on Chemicals (SACC) recommendation to include an illustration of the exposure routes for potentially sensitive or highly exposed populations.

*Response: While "potentially exposed or susceptible subpopulations" is a new definition in TSCA, EPA has, in practice, evaluated risks across populations, with particular attention to workers, pregnant women, children, infants and the elderly, among others ("Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA" – Response to Public Comments (EPA-HQ-OPPT-2016-0636-0076)). The Agency will continue to use and refine its processes for risk evaluations to determine risks to potentially exposed or susceptible subpopulations. Human health and environmental hazards, as well as environmental and human exposures, including potentially exposed or susceptible subpopulations, will be further considered during the development of the TSCA scope documents for all High-Priority Substances.*

*In the review conducted for the final designations, EPA considered reasonably available information to identify the relevant potentially exposed or susceptible subpopulations, such as children, women of reproductive age, workers or consumers. EPA analyzed processing and use information reported under the Chemical Data Reporting (CDR) Rule, which – among other data elements reported – captures manufacturer-reported information regarding a chemical in children's products. These data provide an indication about whether children or other susceptible subpopulations may be potentially exposed to the reported chemical. EPA also used human health hazard information to identify potentially exposed or susceptible subpopulations.*

*Comment:* Other comments (EPA-HQ-OPPT-2019-0131-0012, EPA-HQ-OPPT-2019-0131-0013) cautioned that TSCA prioritization is a process without a pre-determined outcome and the data should drive the priority designation. One commenter (EPA-HQ-OPPT-2019-0131-0013) suggested that "EPA should instead merge the high- and low-priority considerations into a singular section for potential candidates for prioritization."

*Response: EPA agrees that the priority designation should be driven by data. EPA generally expects to provide an explanation for why it chose to initiate the process for the particular chemical substance (e.g., whether EPA views this as a potential candidate for High or Low priority) ("Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act rule (82 FR 33759)). This was to avoid sending strong signals to the public regarding potential risks, even if certain uses of that chemical did not prompt the initiation of prioritization. Note that a proposed or final priority designation is not a finding of unreasonable risk by the Agency. In addition, EPA further notes that the two comment periods provided an opportunity for any interested person to submit additional information before EPA finalized a designation for a candidate chemical substance.*

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0011/EPA-HQ-OPPT-2019-0131-0019) stated, "EPA has violated TSCA § 6(b)(2)(D) by failing to give preference in designating high priority substances to the substances identified by that provision."

*Response: In the Federal Register notice initiating the prioritization process and "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization" (*[ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*), EPA described the three factors that the Agency generally intends to consider for selecting candidates for prioritization. These are (1) Agency priorities, (2) quantity and quality of information, and (3) overall workload to inform the selection of candidates. The statute does not compel EPA to select certain substances, but it does compel the Agency to give preference to some substances. TSCA requires that EPA give preference to chemical substances listed in the 2014 TSCA Work Plan for Chemical Assessments that are persistent and bioaccumulative; known human carcinogens; and/or highly toxic. TSCA section 6(b)(2)(B) further requires that 50 percent of all ongoing risk evaluations be drawn from the 2014 TSCA Work Plan for Chemical Assessments... Aside from these statutory preferences, however, TSCA does not specifically limit how EPA must ultimately select a chemical substance for prioritization. In practice, EPA expects to select for High-Priority Substances those chemicals with the greatest hazard and exposure potential first, consistent with the policy objectives codified in 40 CFR 702.5(a)" (82 FR 33753 at 33758, July 20, 2017).*

*Comment:* Several commenters supported stakeholder engagement and transparency during the prioritization process. According to one commenter (EPA-HQ-OPPT-2019-0131-0004), EPA should continue to engage stakeholders to maintain an open and transparent process that "encourages submission of the most relevant information." Another commenter (EPA-HQ-OPPT-2019-0131-0006) called upon the Agency to provide "greater transparency and clarity" and "more information to ascertain what information [EPA] already has and what information is needed." The commenter also requested that EPA "makes its most up-to-date literature review of each of these candidate chemicals available at the initiation of prioritization stage to interested stakeholders," and that the Agency "clarify what criteria it used to 'narrow' the candidate chemicals from the large sets of chemicals to the candidate lists of 20 high priorities and 20 low priorities." Another commenter (EPA-HQ-OPPT-2019-0131-0011) indicated appreciation for EPA's efforts to keep the regulated community engaged and stated that "transparency and information exchange is critical to the success of future prioritization efforts." Other commenters indicated shortcomings with the transparency of the process and/or provided recommendations for improvements. A commenter (EPA-HQ-OPPT-2019-0131-0011) called for placing all the "reasonably available information" in the dockets for public review. A commenter (EPA-HQ-OPPT-2019-0131-0018) indicated that EPA must be more transparent about the information received during the public comment period following the initiation of the prioritization process and indicate whether EPA used that information to screen the chemical against the criteria for proposing a priority designation, so that

members of the public can comment on such information during the comment period following the proposed designations. The commenter suggested that EPA should strive to be more transparent about the basis for its prioritization decisions and the information used to decide inclusion of a chemical in the 2014 TSCA Work Plan for Chemical Assessments.

*Response: EPA appreciates the feedback regarding engaging with stakeholders and transparency. Regarding the process and criteria used, as described in Unit III.A of the Federal Register Notice initiating prioritization of the candidates for a high priority designation (84 FR 10491, March 21, 2019), EPA used the 2014 Update to the TSCA Work Plan for Chemical Assessments as the starting point for identifying potential candidates and then considered three factors to inform the selection of candidates: (1) Agency priorities, (2) quantity and quality of information, and (3) overall workload ("A Working Approach for Identifying Potential Candidate Chemicals for Prioritization"* [ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*).*

*EPA's intention was to engage with stakeholders in a transparent manner by publishing the notice initiating the prioritization process and the notice with the proposed priority designation, as well as to seek relevant reasonably available information from the public ("Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule" (82 FR 33753-33764, July 20, 2017)). EPA developed a proposed designation document for each candidate chemical substance to identify the information, analysis and basis used to support the proposed High-Priority Substance designation. These documents also include citations for all references used in the literature review of each of these chemical substances, as requested by the commenters, and links to those references that are publicly available. EPA's commitment to public engagement will continue throughout the risk evaluation process of the 20 chemical substances designated as High-Priority Substances.*

<u>Designation Terminology</u>

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0006) called for "greater clarity" for the definitions of High- and Low-Priority Substances and noted that EPA "largely recite[d] the statutory definitions."

*Response: In a previous response to public comment, the Agency articulated its rationale for not elaborating on or modifying statutory standards for High-Priority and Low-Priority Substances: "EPA did not establish the standard for a High Priority designation; Congress did in the definitions of High (and Low) Priority Substances ... The statutory standard for High-Priority designations – that the chemical 'may present an unreasonable risk' based on a 'potential hazard and a potential route of exposure' – is the only place where such a standard appears in TSCA" and "[i]f certain uses of a chemical meet the High-Priority standard, and/or if EPA lacks sufficient information to establish that certain uses do not meet the High-Priority standard, that chemical would not meet the plain language definition of a Low-Priority Substance – that such substance does not meet the standard for designating a chemical substance a high-priority substance" ("Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA" – Response to Public Comments (EPA-HQ-OPPT-2016-0636-0076)). The Agency believes it is appropriate to rely on the statutory standards for designating High-Priority and Low-Priority Substances.*

*Comments:* Several comments (EPA-HQ-OPPT-2019-0131-0006, EPA-HQ-OPPT-2019-0131-0012, EPA-HQ-OPPT-2019-0131-0013, EPA-HQ-OPPT-2019-0131-0018) reiterated EPA's explanation that

designation of a substance as a High-Priority Substance is not a finding of risk. Rather, when prioritization is completed, if a chemical is designated as a High-Priority Substance, EPA will initiate the risk evaluation process. One commenter (EPA-HQ-OPPT-2019-0131-0013) encouraged EPA to provide such disclaimer language widely (e.g. website, Federal Register designation notice, etc.).

*Response: The commenters are correct that designation as a High-Priority Substance is not a finding of unreasonable risk; rather a final designation as a High-Priority Substance will initiate the risk evaluation for the chemical substance. It is through the risk evaluation process that EPA determines whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use (84 FR 44300, August 23, 2019). EPA has included clear language for the final designations of High-Priority Chemical Substances in that regard.*

Timeframe for Providing Chemical Substance Information

*Comments:* Two commenters (EPA-HQ-OPPT-2019-0131-0007, EPA-HQ-OPPT-2019-0131-0013) described the challenges to collecting, identifying, assessing, and submitting specific chemical data in the 90-day comment period following the initiation of the prioritization process, including challenges gathering information that resides with international downstream suppliers, limitations of available data gathering tools, and time and resource requirements. One commenter (EPA-HQ-OPPT-2019-0131-0013) called for additional time during the comment period.

*Response: EPA understands such challenges and has been committed to giving the public and interested stakeholders ample opportunity to provide relevant chemical substance information and comment on key aspects of the prioritization process in general, as well as for a particular chemical substance. The prioritization process was designed, by law, to take no fewer than 9 months, and no greater than 12 months – a timeframe set by Congress to be long enough for interested stakeholders to provide the Agency with relevant, necessary information, but not so long as to stigmatize the chemical substance for being on an EPA "list" without undergoing a formal risk evaluation. Therefore, EPA does not have the discretion to adjust the timeframe for prioritization beyond the 12-month limit established by Congress. Within that 9- to 12-month timeframe under the statute, there are two 3-month comment periods (following initiation and proposed designation for the substances), for a total of 6 months for public comment during the prioritization process. In advance of that process, to facilitate the sharing of information by stakeholders and the general public, EPA opened dockets for each of the 2014 TSCA Work Plan chemicals and an additional general docket to provide the public with a venue for submitting use, hazard, and exposure information on these chemicals (Federal Register Notice announcing the availability of the "Working Approach for Identifying Potential Candidate Chemicals for Prioritization" (83 FR 50366, October 5, 2018). As an additional step to expedite information sharing, EPA has also separately met with stakeholders interested in providing information; summaries of those meetings are docketed for each relevant chemical. EPA encourages interested persons to provide chemical substance information and other comments as early as possible in the process and notes that, for High-Priority Substances, the risk evaluation process includes additional opportunities for comment.*

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0005) agreed that EPA "could use its authority under TSCA 4(a)(1)(A)(i) [to require the development of new information before initiating prioritization] and that it could also use its authority under 4(a)(1)(A)(ii) for chemicals that meet the statutory criteria of being produced and potentially released in substantial quantities or if there is potentially significant exposure," while noting the "difficulty in making a may present unreasonable risk finding as required under 4(a)(1)(A)(i) was among the motivations for amending TSCA, and this difficulty would still need to be overcome." The commenter then stated that "timing requirements might

indeed be difficult to meet in some cases, [but] such difficulty does not remove the clear requirement under 4(a)(2)(B)(i) to make a priority designation within 90 days of receipt of any information requested."

*Response: EPA appreciates the comment regarding the Agency's data collection authority. EPA had sufficient information to complete the prioritization assessment and make final priority designations, and may use information collection authorities for risk evaluation, if needed. For any data needs that are identified, EPA may use the Agency's TSCA authority under TSCA sections 4, 8 or 11, as appropriate. Human health and environmental hazards, as well as environmental and human exposures, including potentially exposed or susceptible subpopulations, will be further considered during the development of the TSCA scope documents for all High-Priority Substances.*

Confidential Business Information

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0011/EPA-HQ-OPPT-2019-0131-0019) urged EPA to implement the requirements of TSCA section 14 when prioritizing chemical substances or during risk evaluation, urging adherence to the requirements for disclosure of certain information by the Agency and the timing for confidentiality claims and substantiations. The commenter stated, "EPA must disclose information as provided under TSCA § 14 and cannot rely on its general FOIA regulations to withhold information that must be disclosed by statute. All claims for confidential protection must be asserted at the time of submission of the information to EPA and must be substantiated at that time unless they meet one of the exceptions specified in TSCA section 14(c)(2)." The commenter indicates that CDR information regarding conditions of use claimed CBI should be timely reviewed by EPA in accordance with TSCA section 14.

*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 its basis for priority designations, including identification of the information and analysis used. EPA generally expects to make the information it uses for decision making publicly available, consistent with the requirements of TSCA section 14.*

International Obligations

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023) suggested that EPA designate mercury as a High Priority Substance to enable the United States to meet its international obligations to reduce mercury use in product manufacturing and industrial processes.

*Response: As indicated by the commenter, EPA agrees that it may take into consideration relevant international actions, such as multilateral environmental agreements, global and regional partnerships, and bilateral or international commitments. However, for this first prioritization, EPA decided to focus on chemicals listed in the 2014 Update to the TSCA Work Plan for Chemical Assessments and considered three factors (i.e., Agency priorities, quantity and quality of information, and overall workload) to inform the selection of candidates ("A Working Approach for Identifying Potential Candidate Chemicals for Prioritization"* [ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*). Mercury and mercury compounds were not included in the 2014 Update to the TSCA Work Plan because, as stated in the 2014 Work Plan Update document, their hazards are already well characterized and the Agency has a strong risk reduction effort in place.*

General Support of the Prioritization Process or Proposed Designation

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0005) supported "EPA's selection of the substances subject to this notice for prioritization for risk evaluation under TSCA." Another commenter (EPA-HQ-OPPT-2019-0131-0006/EPA-HQ-OPPT-2019-0131-0018) supported the pragmatic approach to initiating prioritization using the 2014 TSCA Work Plan for Chemical Assessments list and the approach to consider reasonably available information on exposure potential.

*Comment:* One comment (EPA-HQ-OPPT-2019-0131-0019) indicated that the proposed designation documents for the 20 High-Priority candidate substances establish that the chemicals "may present an unreasonable risk of injury to health or the environment because of a potential hazard and potential route of exposure under the conditions of use." Similarly (EPA-HQ-OPPT-2019-0131-0020) indicated that the proposed chemicals meet the High-Priority Substance definition.

*Response: The Agency appreciates this feedback regarding the prioritization process and the proposed designations.*

Designation Conclusions for Specific Chemicals

*Comment:* Four commenters (EPA-HQ-OPPT-2018-0465-0013, EPA-HQ-OPPT-2018-0465-0014, EPA-HQ-OPPT-2018-0465-0015, EPA-HQ-OPPT-2018-0465-0016) supported the proposed designation of trans-1,2-dichloroethylene as a High-Priority Substance for risk evaluation due to their concerns over the lack of research regarding the human health and environmental impacts of long-term exposure, especially given the likely increase in use since trans-1,2-dichloroethylene could be an alternative to solvents like trichloroethylene. The commenters believe that "additional risk evaluation for this chemical is needed" and urged the Agency to conduct systematic research that can better inform pollution release limits for trans-1,2-dichloroethylene.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0488-0006) described how ethylene dibromide "is supplied as a ready formulated blend into the US in dedicated ISO tanks, with no exposure to the general public or the environment, presenting no risk to human or ecological health."

Comment: A commenter (EPA-HQ-OPPT-2018-0458-0015) stated "more details are needed regarding the data analysis serving as justification for the proposed designation [for TPP]" and that "[a] more detailed explanation regarding the rationale for the Agency's decision would help manufacturers, importers, and downstream users." The same commenter provided information on TPP's PBT characteristics, as well as the relative age of data EPA used to evaluate environmental hazards and general population exposure, and stated "[a]ny data used to evaluate potential environmental hazards should reflect the current state of the science."

*Comment*: Another commenter (EPA-HQ-OPPT 2018-0433-0005/EPA-HQ-OPPT-2018-0446-0012), cited challenges to determining objective grounds for selecting Di-ethylhexyl phthalate (DEHP) as one of the candidates for proposed designation as a High-Priority Substance and recommended that EPA "endeavor to follow the scientifically clarified mechanisms with specific endpoints even if reproductive toxicity and endocrine disruption may result in the same outcome."

*Comment*: A commenter (EPA-HQ-OPPT-2018-0501-0013) suggested that EPA should designate Butyl Benzyl Phthalate (BBP) as "low priority for further action" and submitted information on production levels, exposure levels, toxicity profile, and environmental exposure.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0438-0005) provided information on the potential releases and existing EPA regulations for formaldehyde in stating "there is no basis to conclude that formaldehyde releases from asphalt roofing manufacturing and related industries may present an unreasonable risk of injury to health or the environment warranting a risk evaluation under TSCA." Another commenter (EPA-HQ-OPPT-2018-0438-0008) asked EPA to "find formaldehyde to be a Low Priority Substance. If EPA finds it must rank formaldehyde as a High Priority, the commenter urges EPA to make a determination 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." Another commenter (EPA-HQ-OPPT-2019-0131-0012) noted "recent and dedicated rulemaking for formaldehyde in composite wood products includes an emission limit that was the product of an extensive risk evaluation. As a result, this use should not trigger the high priority criteria, providing the emission standard is adequately considered."

*Comment:* A commenter (EPA-HQ-OPPT-2018-0438-0016) provided general support for designating formaldehyde as a High-Priority Substance, as well as designating fire fighters and emergency medical responders as a susceptible subpopulation, and provided studies of occupational exposures, including studies specific to fire fighters, to formaldehyde and particulates.

*Comment*: One commenter (EPA-HQ-OPPT-2018-0430-0004) stated that the Agency "effectively classified 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8- hexamethylcyclopenta [γ]-2-benzopyran (HHCB) as a low-priority substance. EPA's 2014 Risk Assessment of HHCB 'determined that further assessment of human health risk was not currently needed' for the TSCA uses (as an ingredient in detergents, fabric softeners, dishwashing detergents, and commercial and consumer general purpose cleaners). This conclusion was echoed in OECD's SIDS Initial Assessment Profile (SIAP) for HHCB. The final prioritization rule states that, '[t]hrough the process of prioritization, EPA is ultimately making a judgment as to whether or not a particular chemical substance warrants further assessment.' Low-priority substances are those 'for which risk evaluations are not warranted at the time.'" The commenter (EPA-HQ-OPPT-2018-0430-0012) also stated that EPA "is not required to conduct a risk evaluation of HHCB" and "EPA has still not justified its designation of HHCB as high priority for risk evaluation." However, if EPA designates HHCB as a High-Priority Substance, the commenter is bringing to EPA's attention a list of toxicity studies that are in progress, as well as information regarding volumes of use and concentration of HHCB in products.

*Response: Based on the criteria and considerations set forth in 40 CFR 702.9, EPA determined that all candidate High-Priority Substances may present an unreasonable risk of injury to health or the environment, which is required for designating a chemical substance as high priority. With respect to chemical-specific comments (including those on trans-1,2-dichloroethylene, ethylene dibromide, and DEHP), EPA referenced information submitted by commenters in the proposed designation documents and considered additional information submitted regarding the proposed designations when making the final priority designations. EPA will describe the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that EPA expects to consider in each risk evaluation during the scoping phase of the respective TSCA risk evaluations. Any determination of unreasonable risk for a condition of use will occur as part of the risk evaluation process and will be presented with the draft risk evaluation for which the public and peer reviewers will be given an opportunity to review and comment on.*

*With respect to formaldehyde, EPA was directed by Congress to develop a final rule implementing statutorily established formaldehyde emission standards in composite wood products, by 15 U.S.C. 2697*

*or the Formaldehyde Standards for Composite Wood Products Act. The emission standards for composite wood products were established by Congress and the Formaldehyde Standards for Composite Wood Products Act did not provide EPA with the authority to alter them. The Formaldehyde Standards for Composite Wood Products Act gave the Agency the authority to establish a regulatory program that ensures specific emission standards are met through a certification and testing program for three composite wood products - hardwood plywood, medium-density fiberboard, and particleboard. The Formaldehyde Emission Standards for Composite Wood Products regulatory program does not address or otherwise provide regulatory oversight of the other conditions of use identified for formaldehyde in the August 2019 Proposed Designation of Formaldehyde (CASRN 50-00-0) as a High Priority Substance for Risk Evaluation (see EPA-HQ-OPPT-2018-0438). EPA will consider, as appropriate, the information available through the 'Formaldehyde Emission Standards for Composite Wood Products' regulatory program during the scoping for the risk evaluation process as it relates to composite wood products.*

*With respect to HHCB, EPA recognizes that a TSCA Work Plan Chemical Risk Assessment was published in August 2014, concluding no risk concerns to aquatic organisms and that no further assessment of human health risk was needed, given the analysis done by EPA and information presented in a risk assessment performed by the European Union. However, based on the review conducted for HHCB, EPA identified new environmental and human health studies and is designating HHCB as a High-Priority Substance taking into consideration all of the prioritization criteria, including hazard and exposure potential to HHCB. Other public comments included lists of published studies since the 2014 risk assessment. Reasonable available information will be considered as part of the risk evaluation process under amended TSCA. Additionally, the exposure information will be updated.*

**Review Process for Priority Designation**

Types of Information Considered for Prioritization

*Comment:* Commenters urged the Agency to consider a variety of information sources during the prioritization process, including EPA resources and programs, those administered by other domestic and international governmental agencies, and information from other public and private entities (e.g. Chem View data, OSHA occupational exposure monitoring, REACH registration information) (EPA-HQ-OPPT-2019-0131-0006, EPA-HQ-OPPT-2019-0131-0009, EPA-HQ-OPPT-2019-0131-0011, EPA-HQ-OPPT-2019-0131-0013, EPA-HQ-OPPT-2018-0421-0004, EPA-HQ-OPPT-2018-0433-0006, EPA-HQ-OPPT-2018-0458-0005, EPA-HQ-OPPT-2019-0131-0018). One commenter (EPA-HQ-OPPT-2019-0131-0018) noted that EPA should only rely on conditions of use/exposure information in assessments from other countries if it is applicable in the U.S. and relevant to the prioritization. Another commenter (EPA-HQ-OPPT-2019-0131-0011) noted that EPA needs to obtain full copies of the studies supporting REACH registration and make them publicly available.

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0006) insisted that EPA should rely on reasonably available information and take pragmatic and systematic steps to provide notice and communicate data needs to potentially affected parties should new data be required to be developed (e.g. reasonably available information and read across information, then voluntary call-ins, then TSCA section 8(a) and 8(d) rules, and then section 4). However, another comment (EPA-HQ-OPPT-2019-0131-0011) indicated that EPA must use its authorities under TSCA sections 4 and 8 to obtain information that it "can reasonably generate, obtain, and synthesize" since it is part of the definition of "reasonably available" information in the prioritization rule and in the risk evaluation rule. Furthermore, the commenter indicated that relying on voluntary submissions of information would result in "limited, biased, inaccurate, or incomplete information on the chemicals."

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0010) indicated that "it is critical for EPA to obtain all reasonably available information for high priority candidates needed to complete comprehensive, scientifically accurate risk evaluations, including all conditions of use throughout lifecycle."

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0013) "urged EPA to strive to use the most current data and not rely on older data." Similarly, another commenter (EPA-HQ-OPPT-2019-0131-0018) urged EPA to use the most current and best available science, to address the application of the TSCA scientific standards in the screening review step of the prioritization process, to examine the applicability of advanced approaches for evaluating exposure and bioactivity or toxicity under "other risk-based" screening criteria. This commenter (EPA-HQ-OPPT-2019-0131-0018) recognized that prioritization screening does not warrant the same level of data quality review that a draft risk evaluation does; however, the commenter provided recommendations for improving the exposure potential for prioritization screening purposes, such as looking for up to date and reliable information, paying attention to how the Agency communicates exposure potential in the proposed designation documents to avoid giving the impression of an unreasonable risk finding, clarifying that not every chemical identified as a high priority candidate will have the potential for exposure to general populations or other subpopulations, and improving the public's understanding of how EPA will approach exposure (e.g. consumer uses, use by children, use of an article, etc.).

*Comment*: One commenter (EPA-HQ-OPPT-2019-0131-0020) stated that "EPA's approach for identifying, evaluating and summarizing data on human health hazards for the first 20 chemicals designated as high-priority substances are ad hoc, non-transparent, inconsistent with the Agency's mandate, and likely to have resulted in a biased evidence base." The commenter (EPA-HQ-OPPT-2019-0131-0020) argues that EPA has not used an approach consistent with the TSCA scientific standards or used valid methods to systematically search, evaluate and synthesize data to inform the conclusions on human health hazards.

*Comment*: Another commenter (EPA-HQ-OPPT-2018-0458-0005) stated that "EPA should review and consider all available scientific information regarding the potential for human health and environmental risk associated with Phosphoric acid, triphenyl ester (TPP)," such as biodegradability and the United Kingdom's Environment Agency risk conclusions.

*Comment:* A commenter (e.g., EPA-HQ-OPPT-2018-0465-0003), stated that "[trans-1,2-dichloroethylene], when used in commercially available mixtures, is nonflammable, non-ozone depleting, and nontoxic to the environment as well as human beings," that "[trans-1,2-dichloroethylene] has been included in the SNAP program, and 15 years of research have not determined the chemical to be toxic or carcinogenic. Additionally, no substitutions have been identified that perform as well. Of the available solvents, [trans-1,2-dichloroethylene] is used less frequently than other chemicals and is the best available, as well as a cost effective, option for a cleaning solvent in Electronics Cleaning; Metal Cleaning; Precision Cleaning; and Aerosol Solvent Cleaning whether it be in vapor degreasing, cold cleaning, ultrasonic or aerosol." As such, the commenter requested the chemical be removed from the list of candidates for proposed designation as a High-Priority Substance or create exemptions for "electronics, aviation and metal cleaning."

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0020) pointed out that "despite previously stating that the formaldehyde [Integrated Risk Information System (IRIS) Program] assessment will inform the

prioritization process, the Agency fails to reference the stalled IRIS assessment" and instead cites the 1989 IRIS assessment and the 2011 NRC review in the proposed designation document for formaldehyde. The commenter raises concerns regarding the release of the updated IRIS assessment for public comment.

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023) requested that EPA "[disclose] the full studies to the public without material redaction as required by section 14(b) of TSCA," and that EPA not solely rely on industry-generated summaries that may not faithfully reflect the study findings, in particular studies conducted outside the U.S. under REACH, which EPA should evaluate before using. Similarly, another commenter (EPA-HQ-OPPT-2019-0131-0011) called for EPA obtaining copies of the full studies on which it relies and to make those studies available to the public.

*Response: EPA determined that the 20 chemical substances were suitable candidates for the High-Priority designation based on the Agency's review of the reasonably available information, including relevant information received from the public and other information, as appropriate and cited in the proposed designation documents. The reasonably available information was reviewed against the criteria and considerations set forth in 40 CFR 702.9 and supported a finding that each substance may present unreasonable risk.*

*While EPA appreciates the suggestions on information sources that EPA should use in its prioritization process, the Agency does not believe it would be appropriate to limit its analysis to certain specific data sources. EPA expects to consider the reasonably available information that is consistent with 15 U.S.C. 2625(k) in conducting its review, including information identified by commenters. Furthermore, EPA described in detail its approach to determine the quantity and quality of information reasonably available for prioritization in the document "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization," (*[ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*), and in the discussion of the Agency's working approach to selecting candidates for designation as High Priority Substances, as described in Unit III.A of the Federal Register notice initiating prioritization of the candidates for a high priority designation (84 FR 10491, March 21, 2019).*

*EPA had sufficient information to complete the prioritization assessment and make final priority designations, and may use information collection authorities for risk evaluation, if needed. For any data needs that are identified, EPA may use the Agency's TSCA authority under TSCA sections 4, 8 or 11, as appropriate. Human health and environmental hazards, as well as environmental exposures and human exposures including potentially exposed or susceptible subpopulations, will be further considered during the development of the TSCA scope documents for all High-Priority Substances.*

*With respect to trans-1,2-dichloroethylene, EPA notes that under the SNAP program, EPA listed trans-DCE as an acceptable substitute for specific chemicals in specific applications due to their ozone-depleting characteristics; however, based on the reasonably available information for all identified conditions of use, EPA found that trans-1,2-dichloroethylene may present an unreasonable risk under TSCA, and EPA will conduct a risk evaluation. In the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (82 FR 33753-33764), EPA agreed that the consideration of alternatives is most appropriately considered as part of any risk management rule. Additional information provided will be considered during the risk evaluation of trans-1,2-dichloroethylene.*

*With respect to the use of the IRIS assessment for formaldehyde, EPA will provide details on how the body of scientific information, such as that included in IRIS assessments, will be considered in the risk evaluation process. Similarly, additional information regarding biodegradability of TPP and the United Kingdom's Environment Agency risk conclusions will be considered in the risk evaluation process. The scientific information from any previous assessment will be incorporated into the supplemental documentation on systematic review that will be published for the High-Priority Substances.*

*Through the prioritization and risk evaluation processes, EPA generally considers reasonably available information consistent with the TSCA scientific standards. For prioritization, EPA considered sources of information consistent with the scientific standards in TSCA section 26(h) and (i), including the sources listed in Appendices A and B of the 'TSCA Work Plan Chemicals Methods Document' (February 2012), as required by the 'Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act rule (40 CFR 702.11). EPA used the most recent information from those sources. Also, EPA recognizes that additional information may have been developed for certain chemicals on the 2014 Work Plan and EPA considered updated information as appropriate during the prioritization process. EPA cited the references used in each of the proposed designation documents for High-Priority Substances.*

*As part of the process of using systematic review in the development of risk evaluations, EPA will conduct a comprehensive search of the reasonably available information about the human health and environmental hazards, as well as environmental exposures and exposure to the general population, to consumers, workers, and other potentially exposed or susceptible subpopulations, for each of the 20 High-Priority substances. After this data gathering effort, the Agency will evaluate the quality of the information and integrate the evidence to form overall conclusions about the potential hazards and exposures to support the risk characterization for each of the 20 High-Priority substances in the TSCA risk evaluation documents. This systematic review process will be documented and made public. EPA expects to make the information it uses for decision-making publicly available, consistent with the requirements of TSCA section 14.*

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0004) urged EPA to "continue explicitly outlining the types and quality of data required when listing a chemical for the prioritization process." Another commenter (EPA-HQ-OPPT-2019-0131-0012) would like as much information from the outset to allow the commenter to identify information gaps and areas for comment as the prioritization unfolds, since it is important for stakeholders to contribute information sooner rather than later and most of the information for the risk evaluation will be obtained during the prioritization process.

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0007) commented on the data supporting the EPA's chemical prioritization process. The commenter claims that "EPA has provided only the barest of rationale for high priority selection, in most cases reiterating data used in support of the TSCA workplan listings." The commenter explains that they do not have access to adequate data to understand EPA's rationale in order to comment on this process in a meaningful way, explaining that "As manufacturers and importers of products (articles, components, etc.), we do not have access to information about storage, production volumes or other information specific to the chemical itself. These limitations combined with the broad scope of EPA's comment request make it extremely difficult to collect and provide responses to EPA's information request."

*Comment:* Another commenter (EPA-HQ-OPPT-2018-0433-0005/EPA-HQ-OPPT-2018-0446-0012) cited challenges to determining objective grounds for selecting DEHP as one of the candidates for

proposed designation as a High-Priority Substance and recommended that EPA "endeavor to follow the scientifically clarified mechanisms with specific endpoints even if reproductive toxicity and endocrine disruption may result in the same outcome."

*Response: The Agency points to the discussion of its working approach to selecting candidates for designation as High Priority Substances: "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization," (*[ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*) and the explanation that EPA surveyed the information and checked quality data elements in a step-wise approach, which ensured responsible and timely completion of the prioritization process according to TSCA timelines, and opened dockets to allow for public comment on the prioritization of each of the chemicals.*

*EPA developed a proposed designation document for each substance to identify the information, analysis, and basis used to support the proposed designation as a High-Priority Substance for risk evaluation. The proposed designation documents are available in the docket of each of the High-Priority Substances. Moreover, these documents describe how EPA considered applicable statutory and regulatory requirements and criteria for the prioritization process and supported the High-Priority designations. Specifically, EPA conducted reviews of each of the candidate chemical substances against the criteria and considerations set forth in 40 CFR 702.9 and found that each chemical substance "may present unreasonable risk" under the conditions of use. The information sources used are relevant to the applicable criteria and considerations, and consistent with the scientific standards of TSCA section 26(h), and the sources include, as appropriate, hazard and exposure data listed in Appendices A and B of the "TSCA Work Plan Chemicals: Methods Document" (February 2012) (40 CFR 702.9(b)). Therefore, final designation of each chemical substance as a High-Priority Substance is consistent with TSCA section 26(h) and (i) as required under 40 CFR 702.11. These 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.*

*The final designation as High-Priority Substance immediately initiates the risk evaluation process as described in 40 CFR 702.17. EPA will conduct a systematic review to further characterize the hazards and exposures resulting from the relevant TSCA conditions of use during the scoping phase of the TSCA risk evaluations for chemicals designated as High-Priority Substances.*

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0012) supported the comprehensive identification of the conditions of use in commerce for chemicals during prioritization. The commenter urged EPA to "ensure that the conditions of use are clearly distinguished from those that may cause a chemical to meet the definition for high priority for risk evaluation" by a comprehensive identification of the conditions of use and identification of information needs, as early as possible; consideration of incidental presence of a chemical as an impurity or releases to the aquatic environment or air emissions; and identifying uses with no unreasonable risk as early as possible. Similarly, another commenter (EPA-HQ-OPPT-2019-0131-0013), based on their interpretation of the "fit-for-purpose" approach of the prioritization rule, urged EPA to evaluate chemicals in such a way as to identify the conditions of use that meet the high priority criteria and identify conditions of use that do not present an unreasonable risk at all, stating this approach would "prevent stigmatizing large number of chemicals by incorrectly suggesting that entire categories of chemicals are unsafe for any type of use, regardless of exposure potential." Another commenter (EPA-HQ-OPPT-2019-0131-0025) requested "that EPA consider exempting the import of articles and fluids, adhesives, greases, etc. contained within articles and not designed to be released during the use of the article as early in the prioritization process as possible" and

requested a similar exemption for replacement parts. However, another commenter (EPA-HQ-OPPT-2019-0131-0018) indicated that EPA could designate a chemical substance as High-Priority for risk evaluation based on only a few conditions of use.

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0018) indicated that EPA should be clearer about the conditions of use on which a chemical is proposed as a High-Priority Substance. In particular, the commenter suggests that EPA should clarify that uses "surrounding" pesticides, food additives, drugs or cosmetics excludes them from the TSCA definition of a chemical substance. The commenter supported the use of information from the Chemical Data Reporting rule and reports from the Toxic Release Inventory but encouraged consulting with downstream users to complement the information and to engage stakeholders to develop a process to improve the understanding of conditions of use.

*Comment:* One comment (EPA-HQ-OPPT-2019-0131-0018) supported the use of physical/chemical characteristics and environmental fate data as indicators for ascertaining the potential for persistence and bioaccumulation for prioritization purposes. The comment recommended that EPA consider more recent developments in understanding of persistence and bioaccumulation and update the criteria applied to the 2014 TSCA Work Plan for Chemical Assessments.

*Response: EPA developed a proposed designation document for each chemical substance to identify the information, analysis, and basis used to support the proposed designation as a High-Priority Substance for risk evaluation. The proposed designation documents are in the docket of each of the High-Priority Substances (*[ HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemical-substances-undergoing-prioritization-high" ]*):*

1. *1,3-Butadiene, CASRN 106-99-0, Docket ID number: EPA-HQ-OPPT-2018-0451.*
2. *Butyl benzyl phthalate (BBP) (1,2-Benzenedicarboxylic acid, 1-butyl 2-(phenylmethyl) ester), CASRN 85-68-7, Docket ID number: EPA-HQ-OPPT-2018-0501.*
3. *Dibutyl phthalate (DBP) (1,2-Benzenedicarboxylic acid, 1,2-dibutyl ester), CASRN 84-74-2, Docket ID number: EPA-HQ-OPPT-2018-0503.*
4. *o-Dichlorobenzene (Benzene, 1,2-dichloro-), CASRN 95-50-1, Docket ID number: EPA-HQ-OPPT-2018-0444.*
5. *p-Dichlorobenzene (Benzene, 1,4-dichloro-), CASRN 106-46-7, Docket ID number: EPA-HQ-OPPT-2018-0446.*
6. *1,1-Dichloroethane, CASRN 75-34-3, Docket ID number: EPA-HQ-OPPT-2018-0426.*
7. *1,2-Dichloroethane, CASRN 107-06-2, Docket ID number: EPA-HQ-OPPT-2018-0427.*
8. *trans-1,2-Dichloroethylene (Ethene, 1,2-dichloro-, (1E)-), CASRN 156-60-5, Docket ID number: EPA-HQ-OPPT-2018-0465.*
9. *1,2-Dichloropropane, CASRN 78-87-5, Docket ID number: EPA-HQ-OPPT-2018-0428.*
10. *Dicyclohexyl phthalate (1,2-Benzenedicarboxylic acid, 1,2-dicyclohexyl ester), CASRN 84-61-7, Docket ID number: EPA-HQ-OPPT-2018-0504.*
11. *Di-ethylhexyl phthalate (DEHP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-ethylhexyl) ester), CASRN 117-81-7, Docket ID number: EPA-HQ-OPPT-2018-0433.*
12. *Di-isobutyl phthalate (DIBP) (1,2-Benzenedicarboxylic acid, 1,2-bis(2-methylpropyl) ester), CASRN 84-69-5, Docket ID number: EPA-HQ-OPPT-2018-0434.*
13. *Ethylene dibromide (Ethane, 1,2-dibromo-), CASRN 106-93-4, Docket ID number: EPA-HQ-OPPT-2018-0488.*
14. *Formaldehyde, CASRN 50-00-0, Docket ID number: EPA-HQ-OPPT-2018-0438.*
15. *1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB), CASRN 1222-05-5, Docket ID number: EPA-HQ-OPPT-2018-0430.*

16. *4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA), CASRN 79-94-7, Docket ID number: EPA-HQ-OPPT-2018-0462.*
17. *Phosphoric acid, triphenyl ester (TPP) CASRN 115-86-6, Docket ID number: EPA-HQ-OPPT-2018-0458.*
18. *Phthalic anhydride (1,3-Isobenzofurandione), CASRN 85-44-9, Docket ID number: EPA-HQ-OPPT-2018-0459.*
19. *1,1,2-Trichloroethane, CASRN 79-00-5, Docket ID number: EPA-HQ-OPPT-2018-0421.*
20. *Tris(2-chloroethyl) phosphate (TCEP) (Ethanol, 2-chloro-, 1,1',1"-phosphate), CASRN 115-96-8, Docket ID number: EPA-HQ-OPPT-2018-0476.*

*These documents describe how EPA considered applicable statutory and regulatory requirements and criteria for the prioritization process and supported the High-Priority designations. Specifically, EPA presented the reviews of each of the candidate chemical substances against the criteria and considerations set forth in 40 CFR 702.9 and found that each chemical substance "may present unreasonable risk" under the conditions of use. EPA determined that all candidate High-Priority Substances may present unreasonable risk for at least one condition of use, which is required for designating a chemical substance as a high priority for risk evaluation.*

*Designation as a High-Priority Substance is not a finding of unreasonable risk; rather, a final designation as a High-Priority Substance will initiate the risk evaluation for such chemical substance. Furthermore, 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 actions to address such risks. At that point, TSCA section 6(g) exemptions could be considered.*

*EPA also clarifies that the prioritization process did not include an update of the 2014 Update to the TSCA Work Plan for Chemical Assessments.*

*Comment:* A commenter (EPA-HQ-OPPT-2018-0459-0003) mentioned that in June 2015, the Phthalic Anhyride Producers Panel "submitted a request for correction (RFC) for information pertaining to phthalic anhydride in the Workplan." The commenter noted that "correction of this information would result in the conclusion that phthalic anhydride no longer qualifies for inclusion in the workplan." The commenter also raised concerns about the process, stating that the "Methods Document, 2014 Update, and recent [Regulatory Cooperation Council] summaries were <u>not</u> made available for public review and comment prior to their release." The commenter argued that phthalic anhydride is not widely used in consumer products, is not present in groundwater and ambient air, and release of phthalic anhydride does not suggest the potential for significant environmental and population exposure. The commenter also stated "[f]ollowing EPA's denial of the [Request for Reconsideration], the Panel submitted a Request for Reconsideration . . . and rais[ed] additional concerns about the quality, objectivity, utility, and transparency of the Work Plan process." The commenter stated that EPA provided "no explanation . . . as to what specific information it used to determine that [phthalic anhydride] was 'widely used in consumer products' or that it was present in 'groundwater and ambient air' . . . [and] no opportunity for stakeholder input on the inclusion of [phthalic anhydride] prior to publication of the 2012 Methods Document or the 2014 Update." The commenter also stated that "[a]ll of the information provided in our Request for Correction was readily available at the time OPPT developed the Work Plan substance list . . . [and that] much of the information was developed by EPA itself . . . The suggestion that OPPT did not have this information . . . further highlights its failure to ensure the quality of the disseminated information."

*Response: EPA is not revising the 2014 Update of the TSCA Work Plan in response to this comment. EPA responded to the request for correction in November 2015 (see* [ HYPERLINK "https://www.epa.gov/sites/production/files/2015-12/documents/15003-response.pdf" ]*). Please refer to EPA's response to the request for a detailed response. In March 2017, the Agency responded to the December 2015 request for reconsideration with a third interim response describing how "complexities raised in your request, the quality process in checking and verifying is taking longer than typically anticipated" (see* [ HYPERLINK "https://www.epa.gov/sites/production/files/2017-05/documents/rfr_15003a_interim_20170315.pdf" ]*). While EPA has not yet provided a final response to this request for reconsideration, the information provided was considered for the final designation of phthalic anhydride as a High-Priority Substance. This information will also be considered during the risk evaluation of phthalic anhydride.*

Sufficiency of Information

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0009) stated that "EPA has failed to evaluate whether the available data on the 20 High-Priority candidates are sufficient to conduct robust risk evaluations and, if not, to require testing necessary to fill any data gaps," such as the ones identified in the 2014 TSCA Work Plan Chemical Risk Assessment of HHCB. Similarly, a commenter (EPA-HQ-OPPT-2019-0131-0010) stated that "EPA is mandated to make decisions on high and low priority chemicals based on adequate or sufficient information, respectively." The commenter (EPA-HQ-OPPT-2019-0131-0010/EPA-HQ-OPPT-2019-0131-0020) cited an EPA response to a TSCA section 21 petition and called for EPA to proceed to fill data gaps and generate adequate information for risk evaluation of Tris(2-chloroethyl) phosphate (TCEP) and 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA). Both commenters (EPA-HQ-OPPT-2019-0131-0009, EPA-HQ-OPPT-2019-0131-0010) provided a list of health endpoints that EPA could consider based on EPA's Design for the Environment program and the Green Screen protocol. And another commenter (EPA-HQ-OPPT-2019-0131-0013) called upon EPA to define "sufficiency of information" and clarify how the Agency would treat exposure data gaps in the pre-prioritization process in order to "help industry submit necessary information during the prioritization process."

*Response: EPA has purposefully decided not to establish a threshold for "sufficient information." The Agency does not wish to create a bright line that could lead to High-Priority designations and the initiation of risk evaluations because EPA bound itself to an inflexible "sufficiency" standard ("Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA" – Response to Public Comments (EPA-HQ-OPPT-2016-0636-0076)). EPA had sufficient information to complete the proposed prioritization assessment and may use information collection authorities for risk evaluation, if needed. For data needs that are identified, EPA may use the Agency's authority under TSCA sections 4, 8 or 11, as appropriate. Furthermore, EPA notes that section 4(a)(2)(B)(ii) indicates: "information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability."*

Storage Near Significant Sources of Drinking Water

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0004) asked the Agency to define "near" and "significant" in the context of "near significant sources of drinking water" and suggested the use of EPA's "Drinking Water Mapping Application to Protect Source Waters (DWMAPS)" to do so.

*Comment*: Another comment (EPA-HQ-OPPT-2019-0131-0018) indicated that EPA used a reasonable approach for screening the first 20 chemicals as High-Priority Substances; however, EPA should

consider use of improved exposure models that can better predict fate and environmental partitioning into water sources.

*Response: EPA believes that Congress included "storage near significant sources of drinking water" as a potential human health hazard and exposure consideration, given that chemicals that are stored near water have a greater potential to enter that water ("Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA" – Response to Public Comments (EPA-HQ-OPPT-2016-0636-0076)).*

*In each proposed designation document, EPA explains its analysis of the "storage near significant sources of drinking water" under 40 CFR 702.9 as follows:*

> *"The statute specifically requires the Agency to consider the chemical substance's storage near significant sources of drinking water, which EPA interprets as direction to focus on the chemical substance's potential human health hazard and exposure. EPA reviewed reasonably available information, specifically looking to identify certain types of existing regulations or protections for the proposed chemical substances. EPA considered the chemical substance's potential human health hazards, including to potentially exposed or susceptible subpopulations, by identifying existing National Primary Drinking Water Regulations under the Safe Drinking Water Act (SDWA; 40 CFR Part 141) and regulations under the CWA (40 CFR 401.15). In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under EPCRA (Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), CERCLA (Hazardous Substances), and CAA (Section 112(r) Regulated Chemicals for Accidental Release Prevention). Regulation by one of these authorities is an indication that the substance is a potential health or environmental hazard which, if released near a significant source of drinking water, could present unreasonable risk of injury to health or the environment."*

*EPA has also considered suggestions for how "storage near significant sources of drinking water" might be interpreted and applied, but the Agency has not attempted to specifically define the individual terms in this phrase ("Procedures for Prioritization of Chemicals for Risk Evaluation under TSCA" – Response to Public Comments (EPA-HQ-OPPT-2016-0636-0076)).*

*Comment:* Another commenter (EPA-HQ-OPPT-2019-0131-0004) urged the Office of Pollution Prevention and Toxics within EPA's Office of Chemical Safety and Pollution Prevention (OCSPP) to coordinate with the Office of Ground Water and Drinking Water to "effectively prioritize chemicals which have the potential of impacting drinking water sources, both ground water and surface water."

*Response: EPA expects to consider overarching Agency priorities in selecting chemicals for prioritization, including information and analysis conducted by the Office of Ground Water and Drinking Water. EPA's document, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization," (*[ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*), states that the process to select chemicals "may include . . . chemicals that other EPA program offices have deemed a priority for their program and suitable for current prioritization."*

**Submitted Data and Information**

Hazard and Exposure Potential:

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0011) provided information for all candidate chemicals for High-Priority designation regarding: (1) assessments conducted by other federal agencies/countries, (2) information from ChemView, (3) availability of workplace exposure data in OSHA's database, and (4) REACH registration and evaluation information. The commenter highlights the dermal test data for p-dichlorobenzene, 1,2-dichlorobenzene, and 1,2-dichloropropane.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0430-0005) provided a list of "new scientific literature on 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB) published since the 2008 EPA Work Plan Risk Assessment, which indicates greater potential harm from this chemical than previously assumed."

*Comments:* An anonymous commenter (EPA-HQ-OPPT-2018-0438-0003) raised issues concerning formaldehyde and pointed to "extensive review within the European Union due to its classification as a carcinogen and mutagen." Another commenter (EPA-HQ-OPPT-2018-0438-0009), concerned about formaldehyde, mentioned that "exposure to formaldehyde presents numerous cancer and non-cancer hazards to human health. These include (but are not limited to): Headache, Nausea, Respiratory irritation, Eye irritation, Skin irritation, Allergic contact dermatitis, Eczema, Pulmonary edema, Asthma, Changes in lung function, Gastrointestinal irritation, Neurological effects, Impaired fetal development, Carcinogenicity (in general and specifically Nasopharyngeal cancer, Sinonasal cancer, Lymphohematopoietic cancers). Assessments of formaldehyde by authoritative bodies (U.S. National Toxicology Program; International Agency for Research on Cancer) have concluded that it is carcinogenic—presenting several types of cancer in humans. In addition, recent studies provide mechanistic support for the relationship between formaldehyde and leukemia."

*Comment*: A commenter (EPA-HQ-OPPT-2018-0501-0012) provided a reference related to the biodegradability that was not included in the proposed designation document for Butyl benzyl phthalate (BBP).

*Comment:* A commenter (EPA-HQ-OPPT-2018-0427-0004) stated that EPA has not addressed the issues raised by the commenter related to potential exposure to and persistence and bioaccumulation potential of 1,2-dichloroethane in the 2014 TSCA Work Plan. The commenter indicates that correction of the information would result in the conclusion that 1,2-dichloroethane no longer qualifies for inclusion in the Work Plan. The commenter (EPA-HQ-OPPT-2018-0427-0004) further indicated that three data sources (NHANES, NATA, NCOD) indicate a low potential for exposure. More recent data also provides further evidence for a low potential for exposure. The commenter provided information that "may not be new; however, it is relevant and readily available and should be considered."

*Comment*: A commenter (EPA-HQ-OPPT-2018-0427-0006) provided information to inform the screening review conducted pursuant to 40 CFR 702.9(a) for 1,2-dichloroethane. The commenter (EPA-HQ-OPPT-2018-0427-0016) supplemented and updated their previous submission.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0446-0004/ EPA-HQ-OPPT-2018-0446-0011) provided information to inform the review conducted pursuant to 40 CFR 702.9(a) for p-dichlorobenzene and stated that many small businesses and households use p-dichlorobenzene in toilet/urinal care products since it is an inexpensive product that is proven effective. In the opinion of the commenter, "[s]ince there are no direct replacement products that are as effective or as long-lasting as PDCB, consumers may use more of the alternative product causing greater risk for exposure."

*Comment*: A commenter (EPA-HQ-OPPT-2018-0446-0013) provided information regarding the use of p-dichlorobenzene, as well as a summary of existing regulations and comments regarding the proposed designation document. The commenter urged EPA to consider the extensive existing regulatory framework for manufacturers and polymerization users of p-dichlorobenzene during scoping.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0428-0013) indicated that 1,2-dichloropropane is used as an intermediate to produce other products in closed systems and urged EPA to take into account the extensive regulatory framework already in place as it defines the scope of the risk evaluation to be conducted under TSCA.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0451-0004) mentioned that it is "working to provide a central resource for the 1,3-butadiene industry in the US . . . [and] is currently updating its factual product stewardship manual with information regarding the uses and handling of 1,3-butadiene. This information will be provided to EPA when available." In a follow up comment (EPA-HQ-OPPT-2018-0451-0018) described additional hazard and exposure information that EPA should use, such as information relating to human health and occupational exposure. The commenter (EPA-HQ-OPPT-2018-0451-0018) emphasized that commercial and consumer products that contain 1,3-butadiene are most likely limited to rubber and plastic products, and exposure to 1,3-butadiene is very limited because 1,3-butadiene is used as a monomer to create polymers and is not used as a formulated ingredient.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0438-0008) stated "[s]ince promulgation of the 1999 MACT Standard, the fiber glass industry has voluntarily undertaken a major effort to replace phenol formaldehyde ([']PF[']) binders. Non-PF binder products now represent the vast majority of the fiber glass industry. Mineral wool companies that use formaldehyde are starting to use or explore the use of non-formaldehyde substitutes. According to 2010 emissions data, there has been a dramatic decrease in hazardous air pollutants since 1999."

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0014) provided additional information regarding uses, production volume, production sites, and impurities for phthalic anhydride, butyl benzyl phthalate, formaldehyde and 1,3-butadiene.

*Response: EPA appreciates the chemical-specific information submitted during the two comment periods. EPA referenced chemical-specific information submitted by commenters after initiation in the proposed designation documents and considered additional information submitted regarding the proposed designations when making the final priority designations. EPA will describe the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that EPA expects to consider in each risk evaluation during the scoping phase of the respective TSCA risk evaluations. Any determination of unreasonable risk for a condition of use will occur as part of the risk evaluation process and will be presented with the draft risk evaluation that the public and peer reviewers will be given an opportunity to review and comment on.*

*EPA identified reasonably available environmental and human health hazard information to evaluate potential hazard of the chemical, including studies reporting developmental toxicity and neurotoxicity. EPA will conduct a systematic review to further characterize the hazards and exposures resulting from the relevant TSCA conditions of use during the scoping phase of the TSCA risk evaluations for chemicals designated as High-Priority Substances.*

*In the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (82 FR 33753-33764), EPA agreed that the consideration of alternatives is most appropriately considered as part of any risk management rule.*

Potentially Exposed or Susceptible Subpopulations

*Comment:* A commenter (EPA-HQ-OPPT-2018-0438-0007) stated "[t]he general population, as well as vulnerable subpopulations, are commonly exposed to formaldehyde through both indoor and outdoor air pollution (e.g., industrial processes and automotive exhaust). Workplace exposures are also a significant concern, given the breadth of industries in which formaldehyde is known to be used or otherwise present."

*Comment*: A commenter (e.g. EPA-HQ-OPPT-2018-0421-0013) provided technical reports for some of the proposed High-Priority Substances that provide an overview of potentially exposed or susceptible subpopulations for these chemicals.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0451-0014) supported EPA's high-priority designation of 1,3-butadiene and also supports designating firefighters and emergency medical personnel as susceptible populations. Firefighters are exposed to 1,3-butadiene in municipal and wildland smoke that emanates from fires, and emergency medical personnel are exposed to 1,3-butadiene from the diesel exhaust that emanates from fire apparatus and ambulances. The commenter cites IARC classification of 1,3-butadiene as carcinogenic to humans.

*Comment:* A commenter (EPA-HQ-OPPT-2018 0462-0007) pointed to data from the National Toxicology Program showing that 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA) can induce aggressive uterine cancer in rats, potentially by altering steroid activity." The same commenter (EPA-HQ-OPPT-2018-0503-0005) specified that "[d]ibutyl phthalate (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." The commenter (EPA-HQ-OPPT-2018-0501-0005) also indicates that "benzyl butyl phthalate (BBP) inhibits testosterone production and has effects on sexual differentiation in male animals and mammary gland growth in female animals." And the same commenter (EPA-HQ-OPPT-2018-0433-0006) indicated that di-ethylhexyl phthalate (DEHP) has a "wide range of effects," such as DNA modifications, metabolic disorders, effects on the female reproductive system, adverse birth outcomes and disrupt thyroid hormone biology.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0459-0003) forwarded an analysis that included the results of 3 years of reporting under Washington State's Children's Safe Product Act (CSPA) and the authors "assigned phthalic anhydride the lowest total priority index score of zero (based on toxicity and exposure)." The commenter indicated that this conclusion reflects the low potential for exposure to phthalic anhydride and contributed to the removal of the chemical from the list of chemicals subject to reporting under the CSPA.

*Response: EPA will consider reasonably available information to characterize the environmental and human exposures, including potentially exposed or susceptible subpopulations, resulting from the conditions of use during the scoping phase of the TSCA risk evaluations for chemicals designated as High-Priority Substances.*

*As indicated in the proposed designation documents, when relevant, workers will be considered potentially exposed or susceptible subpopulations, such as firefighters and emergency medical personnel. EPA will also consider human health hazard information to identify potentially exposed or susceptible subpopulations, such as developmental effects, uterine cancer, or reproductive system effects. With respect to concerns raised regarding workplace exposures to formaldehyde, workers were identified as a subpopulation that may be potentially exposed or susceptible subpopulation in the proposed designation document for formaldehyde.*

Conditions of Use or Significant Changes in Conditions of Use

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0008) described the uses of phthalic anhydride, formaldehyde, 1,3-butadiene, butyl benzyl phthalate, diisobutyl phthalate, dicyclohexyl phthalate, triphenyl phosphate, 1,1,2-trichloroethane, 1,2-dichloroethane, dibutyl phthalate, diethylhexyl phthalate, and tetrabromo BPA in paints, coatings, sealants and adhesives, with the goal of "assist[ing] EPA with identifying accurate uses, exposures and environmental releases."

*Comment:* A commenter (e.g., EPA-HQ-OPPT-2018-0421-0006) identified a variety of uses in the aerospace industry for most of the candidate High-Priority Substances.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0465-0009) provided information regarding the use of trans-1,2-dichloroethylene in the formulation of products "which are distributed and sold to industrial end users, primarily for use in the area of medium and heavy-duty solvent precision cleaning, rinsing, and drying."

*Comment:* Two commenters (EPA-HQ-OPPT-2018-0488-0006, EPA-HQ-OPPT-2018-0488-0007) described how ethylene dibromide is involved in the production of fuels: "AvGas . . . a fuel that powers piston-engine agricultural aircrafts" and that there is "no current replacement or alternative fuel for AvGas." Furthermore, the use in fuels is "subject to the EPA/FAA Piston Fuel Aviation Program which was formed in response to EPA's request to reduce or eliminate [tetraethyllead] based additives in aviation fuels. This is a multi-industry stakeholder process that is not due to be complete until mid-2020. Once a suitable alternative is identified, it will take a further 2-3 years to get the fuel on the market and specifications and legislative changes."

*Comment*: Another commenter (EPA-HQ-OPPT-2019-0131-0019) indicated that EPA has failed to identify instances where the chemical substances are known or reasonably foreseen to be used or disposed of in hydraulic fracturing fluids or produced water associated with oil and gas extraction, including: 1,1-dichloroethane, triphenyl phosphate, 1,3-butadiene, formaldehyde, phthalic anhydride, dibutyl phthalate, benzyl butyl phthalate, di(2-ethylhexyl)phthalate, 1,4-dichlorobenzene, 1,2-dichlorobenene, and benzyl butyl phthalate.

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0022) indicated that they use four of the proposed chlorinated solvents (o-dichlorobenzene, trans-1,2-DCE, 1,2-dichloroethane, and 1,1,2-trichloroethane); each of the five proposed phthalates (DBP, BBP, DEHP, DIBP, and DCHP); all three of the halogenated flame retardants (TBBPA, TCEP, and TPP) and three of the other substances (1,3-butadiene, formaldehyde, and phthalic anhydride). The comment includes additional information describing how the chemicals are used in automobiles and stated that "exposure to passengers to those substances resulting from their use in automobiles is expected to be negligible."

*Comment:* One commenter (EPA-HQ-OPPT-2018-0451-0004) described varying degrees of purity in 1,3-butadiene used in certain manufacturing processes. Another commenter (EPA-HQ-OPPT-2018-0451-0003) argued that 1,3-butadiene is "added in controlled quantities through a closed system so that occupational and environmental exposure is minimal . . . [and that c]onsumer exposure is negligible because the polymerization process results in the complete conversion of the monomer . . . Therefore, EPA should conclude that 1,3-butadiene presents negligible risk and these uses should be excluded from the scoping document." Another commenter (EPA-HQ-OPPT-2019-0131-0012) described how 1,3-butadiene "may be indirectly present at low levels" in synthetic rubber and "generally would favor including impurities as a condition of use in the risk evaluation in exchange for the future benefit associated with the preemptive effect of EPA's review."

*Comment:* A commenter (EPA-HQ-OPPT-2018-0430-0005) provided a list of information related to use of HHCB in fragranced products and suggested that "[t]here is considerably more information available now about which consumer products contain HHCB than there has been previously due to significant advancements in both voluntary and regulated fragrance ingredient disclosure effort" and that EPA should request that manufacturers identify additional uses.

*Comment*: A commenter (e.g. EPA-HQ-OPPT-2018-0421-0013) provided technical reports for all proposed High-Priority Substances that provide an overview of the manufacturing, processing, importation, distribution in commerce, and disposal of these chemicals.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0427-0018) further refined their initial statements and indicated that "1,2-dichloroethane appears in trace amounts as an impurity in industrial adhesives only," and such adhesives "are used in a wide range of uses that include paper converting, labeling, and tissue and towel applications."

*Response: EPA referenced information submitted by commenters in the proposed designation documents and considered reasonably available information, including public comments, when making the final priority designations. EPA will consider the relevant information on conditions of use submitted by commenters during the scoping phase of the respective TSCA risk evaluations. Any determination of unreasonable risk for a condition of use will occur as part of the risk evaluation process and will be presented with the draft risk evaluation that the public and peer reviewers will be given an opportunity to review and comment on.*

*In the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (82 FR 33753-33764), EPA agreed that the consideration of alternatives is most appropriately considered as part of any risk management rule.*

**Comments Related to the Long-Term Prioritization Process**

Future and Long-Term Pre-Prioritization Efforts

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0007) stated that "[i]t is critical that the approaches EPA adopts for the selection of high priority and low priority candidates for further evaluation be consistent with the intent of the Lautenberg Chemical Safety Act (LCSA), because it will set precedent for how EPA identifies, evaluates and regulates chemicals in the future." Another commenter (EPA-HQ-OPPT-2019-0131-0012) reiterated the importance of a timely and transparent process for prioritization and assessing existing chemicals; to that end, the commenter suggested that EPA "move ahead with scheduling all 2014 Work Plan chemicals for prioritization to make the process predictable and routine" and "engage in further stakeholder discussions on its vision for the long-term to 'bin' all of the other chemicals on the TSCA Inventory for prioritization."

*Comment*: Another commenter (EPA-HQ-OPPT-2019-0131-0006/EPA-HQ-OPPT-2019-0131-0018) requested that EPA "finalize and release its 'proof of concept' white paper on 'longer term' prioritization soon" with explanations on the use of New Approach Methodologies and other 21st century tools and sources of information. In addition the commenter suggested the inclusion of the following topics on the long-term "white paper": binning; screening criteria; approach to both High- and Low-Priority candidates; sources of information for Low-Priority candidates; exposure (use of advanced approaches and models); evaluating Unknown or Variable Composition (UVCB substances); storage near significant sources of drinking water; and how prioritization approaches are evolving. The commenter indicated that EPA should also develop guidance on how the Agency will address best available science and reduction in animal testing. Another commenter (EPA-HQ-OPPT-2019-0131-0013) urged EPA to "clearly define binning and to make sure it is well understood that 'binning' is not the same as 'categories.'"

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0010) indicated that "EPA must proceed with identifying, expeditiously evaluating, and limiting dangerous chemicals from the more than 40,000 existing chemicals on the active TSCA inventory in a manner based on the best available science that will protect our most vulnerable populations."

*Response: The Agency appreciates this feedback and will take this information into consideration as it develops a longer-term prioritization strategy. As EPA stated in the document, "A Working Approach for Identifying Potential Candidate Chemicals for Prioritization," (*[ HYPERLINK "https://www.epa.gov/sites/production/files/2018-09/documents/preprioritization_white_paper_9272018.pdf" ]*), the approach for identifying candidates for prioritization is expected to evolve over time as EPA develops expertise in identifying chemicals to enter prioritization, as well as in conducting prioritization and risk evaluations. Additionally, this document states that "subsequent steps will include a white paper and future public workshops and discussion."*

*For the long-term, EPA's goal is to develop a procedure to inform selection of candidates for prioritization that integrates information from new-approach methodologies (NAMs) and information from traditional studies (e.g., hazard, exposure, engineering, fate), and that builds on the TSCA Work Plan for Chemical Assessments methodology. Consistent with the "Working Approach for Identifying Potential Candidate Chemicals for Prioritization" document, EPA also will consider federal government priorities and other interests when considering candidates for prioritization.*

Use of Categories

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0013) indicated that in future efforts, EPA may select categories of similar chemicals to prioritize together. The commenter emphasized the difficulties associated with categories of similar chemicals and urged EPA to "make sure that the categories have clear and well-defined boundaries . . . [and] further clarify the criteria used to define chemical categories, such as similarities on structure, biology, or use . . . [and] provide a CAS Number for each chemical in the entire category. . . [and ensure] that the chemical accurately depicts the level of concern appropriate for all the other chemicals associated with the category."

*Response: As stated in the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (82 FR 33753-33764), "TSCA section 26 provides EPA with authority to take action on categories of chemical substances." Furthermore, "should EPA determine to prioritize a category of chemical substances, EPA would describe the basis for such a determination in the Federal Register notice published to initiate prioritization" and "EPA will provide an explanation of the rationale for initiating the process on the chemical substance, thus ensuring the public has notice and an opportunity to comment on any decision to prioritize a category of chemical substances."*

**Comments Related to Risk Evaluation**

Types of Information Considered and Overall Approach for Risk Evaluation

*Comment:* Commenters also urged the Agency to consider a variety of information sources during the overall risk evaluation process, including EPA resources and programs (*e.g.*, the Integrated Risk Information System (IRIS) Program), those administered by other domestic and international governmental agencies (e.g. local governments, OSHA, NIOSH), and information from other public and private entities (EPA-HQ-OPPT-2019-0131-0009, EPA-HQ-OPPT-2019-0131-0010, EPA-HQ-OPPT-2019-0131-0011, EPA-HQ-OPPT-2019-0131-0012, EPA-HQ-OPPT-2019-0131-0013, EPA-HQ-OPPT-2019-0131-0014, EPA-HQ-OPPT-2018-0421-0004, EPA-HQ-OPPT-2019-0131-0019, EPA-HQ-OPPT-2018-0421-0013). One commenter (EPA-HQ-OPPT-2019-0131-0010) cited the National Academies of Sciences 2017 report on implementation of systematic review and recommended that "EPA should build on existing high-quality reviews to incorporate new studies, and then use this updated systematic review as basis for its assessment," including IRIS assessments. Similarly, a commenter (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023) stated that EPA should rely on IRIS assessments and not revisit the findings unless new peer-reviewed data, evaluated with accepted systematic review methodologies, informs the IRIS assessment evaluation on the weight of the evidence. Another commenter (EPA-HQ-OPPT-2019-0131-0019) indicated that EPA must accurately describe the information it relies on, particularly the data from the European Chemicals Agency (ECHA).

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0011/EPA-HQ-OPPT-2019-0131-0019) raised concerns related to public disclosure and urged EPA to "obtain the full studies if it is to rely on them for its risk evaluations," to "request that submitters always provide copies of full studies, as well as underlying data whenever reasonably available or obtainable," and to make these studies and data publicly available.

*Comment*: Commenters (EPA-HQ-OPPT-2019-0131-0019, e.g. EPA-HQ-OPPT-2018-0421-0013) urged EPA to accurately identify all relevant potentially exposed or susceptible subpopulations (PESS), since the lists presented in the proposed designation documents are far from complete. Similarly, another commenter (e.g. EPA-HQ-OPPT-2018-0421-0013) called for EPA to "consider the special vulnerability of fetuses and children to chemicals."

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0019) indicated that EPA needs to ensure that environmental justice is appropriately considered, analyzed, and addressed in the risk evaluation process by incorporating an environmental justice analysis into the final prioritization designations and ensuring meaningful involvement of environmental justice communities as it moves forward. Another commenter (EPA-HQ-OPPT-2019-0131-0016) urged EPA to use rates of consumption of fish and other aquatic life that are representative of tribal lifeways. Similarly, another commenter (e.g. EPA-HQ-OPPT-2018-0421-0013) called for consideration of environmental justice and tribal concerns in the risk evaluations, for EPA "to implement a systematic approach to identifying and reducing toxic exposures experienced by minority, low-income, and tribal populations" during scoping.

*Comment*: Another commenter (EPA-HQ-OPPT-2019-0131-0017) encouraged EPA to thoroughly understand the conditions of use once risk evaluation is initiated. The information influences the characterization of potential exposures and releases. Also, EPA should understand which "uses can be critical to, and provide, important societal benefits." The commenter also offered to assist EPA in future efforts to gather information regarding conditions of use and identify and accommodate chemical substitution.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0427-0012) indicated that 1,2-dichloroethylene is "used almost exclusively as a precursor in the production of vinyl chloride which is subsequently used to produce polyvinyl chloride (PVC)." They urged EPA to take into account the regulatory framework already in place that manage the release of 1,2-dichloroethylene into the environment administered by several EPA environmental statutes.

Comment: A commenter (EPA-HQ-OPPT-2018-0459-0003/EPA-HQ-OPPT-2018-0459-0013) provided a summary of ways that facilities that manufacture and use phthalic anhydride comply with regulatory and analytical processes, including the Clean Air Act (CAA), the Safe Drinking Water Act (SDWA), the Clean Water Act (CWA) and the Resource Conservation and Recovery Act (RCRA). The same commenter (EPA-HQ-OPPT-2018-0459-0003) stated that "phthalic anhydride is not widely used in consumer products, is not present in groundwater and ambient air, and release of phthalic anhydride does not suggest the potential for significant environmental and population exposure."

*Comment*: One commenter (EPA-HQ-OPPT-2018-0438-0018) provided a list of "adequately regulated" conditions of use, citing existing regulations and standards implemented by EPA, the Department of Housing and Urban Development, the Food and Drug Administration, the Occupational Safety and Health Administration, and the Consumer Product Safety Commission, and suggested for consideration finalized and ongoing international chemical reviews, information on potential susceptible subpopulations, human health hazards and environmental hazards, and information on refractive index and dielectric constants.

*Comment*: Commenters urged EPA to consider all conditions of use (EPA-HQ-OPPT-2019-0131-0012, EPA-HQ-OPPT-2019-0131-0023). Other commenters urged EPA to consider all exposure pathways (EPA-HQ-OPPT-2019-0131-0019, EPA-HQ-OPPT-2019-0131-0023), even when regulated under other EPA authorities. One of those commenters (EPA-HQ-OPPT-2019-0131-0019) indicated that EPA does not need to attribute every environmental release of a chemical to a particular condition of use during the risk evaluation stage. One of the commenters (EPA-HQ-OPPT-2019-0131-0023) also indicated that by EPA excluding "discontinued manufacturing, processing and use activities from the definition of 'conditions of use' and therefore from the scope of risk evaluations," EPA is excluding 'reasonably

foreseen' conditions of use, and the goals of TSCA would be defeated if EPA completes a risk evaluation and then the chemical re-enters the market place free from any restriction or determination of risk.

*Comment*: Another commenter (EPA-HQ-OPPT-2019-0131-0008) raised concerns regarding excluding conditions of use, stating that "a situation could arise where EPA excludes a condition of use in a manner that compromises comprehensive review and limits federal pre-emption." The commenter went on to state that even when a condition of use is adequately controlled, "EPA should still include it in the final risk evaluation to describe EPA's rationale for concluding the use poses no unreasonable risk." Another commenter (EPA-HQ-OPPT-2019-0131-0016) indicated that environmental statutes do not guarantee protection from exposures (e.g., landfills in Alaska, unregulated groundwater well systems, open barrels for burning) and indicated that "EPA must evaluate disposal as a condition of use for all 20 of the proposed high priority chemicals in order to comply with TSCA" and described why disposal of the proposed High-Priority chemicals should be evaluated to properly characterize the risk to tribal peoples. Similarly, another commenter (EPA-HQ-OPPT-2018-0465-0018) indicated that risk evaluations fail to "conduct health-protective aggregate exposures" by excluding exposures from scenarios that could be regulated under other statues. However, another commenter (EPA-HQ-OPPT-2019-0131-0025) "encourage[d] EPA to focus on conditions of use that are not currently regulated by other federal regulatory agencies" and to recognize standards set by other federal agencies as protective.

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0025) indicated that it is critical "that decisions on conditions of use be made rapidly and with certainty" and, once risk evaluations are completed, clearly articulate "findings of 'no unreasonable risk' associated with specified conditions of use."

*Comment*: A commenter (EPA-HQ-OPPT-2018-0446-0011) requested that EPA exclude p-dichlorobenzene conditions of use related to toilet care in the scoping document due to its low production volume and low exposure, since EPA has already assessed potentially exposed populations and hazard potentials of toilet care uses in the Human Health Risk Assessment in support of Registration Review (September 27, 2018) and the Final Guidelines for Carcinogen Risk Assessment (March 2005). These assessments "determined the minimal exposure to urinal/toilet blocks is not significant" and p-Dichlorobenzene as "Not Likely to be Carcinogenic to Humans."

*Comment:* Another commenter (EPA-HQ-OPPT-2018-0458-0005) requested that "[i]f EPA determines that TPP is a high priority substance for TSCA risk evaluation, it should transparently and objectively consider only relevant conditions of use when identifying exposure scenarios and determining any future regulatory actions."

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0016) urged "EPA to consider the impacts of legacy use of these 20 chemicals on tribal populations." Similarly, other commenter (EPA-HQ-OPPT-2019-0131-0023, e.g. EPA-HQ-OPPT-2018-0421-0013) also indicated that EPA must address all ongoing uses of legacy products and associated disposal activities.

*Comment*: Another commenter (EPA-HQ-OPPT-2019-0131-0019) stated that EPA should include byproducts, metabolites or degradation products in the risk evaluations. Similarly, another commenter (EPA-HQ-OPPT-2018-0465-0018) pointed out arbitrary exclusion of exposure scenarios impacting non-worker populations, such as EPA did in the 1,4-dioxane draft risk evaluation.

*Comment*: Several commenters raised concerns with *de minimis* amounts and impurities in products. One commenter (EPA-HQ-OPPT-2019-0131-0008) supports a "case-by-case approach" to exclude *de minimis* exposures from scope when justified: "We would discourage EPA from adopting a blanket policy of excluding such exposures. [The commenter] can envision a situation where EPA could include de minimis exposure in a final risk evaluation, if only to document and integrate evidence of de minimis exposures to support a conclusion of no unreasonable risk." Another commenter (EPA-HQ-OPPT-2019-0131-0012) indicated that EPA consider the incidental presence of a chemical as impurity during prioritization and risk evaluation. Another commenter (EPA-HQ-OPPT-2019-0131-0014) requested a clarification from EPA regarding the manufacture or import of High-Priority Substances "if they are distributed in commerce solely as an impurity or in small amounts." Another commenter (EPA-HQ-OPPT-2019-0131-0025) indicated the challenges to identifying *de minimis* amounts of chemicals in articles and components in their supply chain. The commenter explains that such *de minimis* amounts are not tracked because "the underlying assumption [is] that the risk of exposure is negligible." The commenter (EPA-HQ-OPPT-2019-0131-0025) provided the following examples: 1,2-dichloropropane (CAS# 378-87-5) was identified as a chemical that may be used in the manufacturing and/or present in the front windshield assembly of certain vehicles; the presence of this chemical, bound up in the windshield assembly, poses little to no risk of exposure. Similarly, the use of 1,3-butadiene (CAS# 106-99-0) in manufacturing a bumper or door handle assembly does not mean that either of those articles present a concern (condition of use) that warrants further evaluation.

*Comment*: A commenter (EPA-HQ-OPPT-2018-0465-0018) pointed out EPA's failure to determine robustness of the databases on human health and ecological hazard and exposure, and to account for such deficiencies, with two main consequences: EPA does not take advantage of its enhanced ability to fill data gaps before a risk evaluation, and impacts the adequacy of the benchmark by not including an additional uncertainty factor to account for the data deficiencies.

*Comment*: Another commenter (e.g. EPA-HQ-OPPT-2018-0421-0004) indicated that several studies provide evidence that 18 of the 20 candidate High-Priority Substances should be treated as endocrine disruption compounds, and the "risk evaluation should review this evidence in determining whether they pose unreasonable risk to human health due to the adverse outcomes caused by endocrine disruption." The commenter offered suggestions on tests that should be performed to evaluate endocrine disruption and requested that the Agency require testing for 1,1-dichloroethane and phthalic anhydride.

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0010/EPA-HQ-OPPT-2019-0131-0020) stated that "EPA should conduct a cumulative risk assessment for phthalates, chlorinated solvents, and any other chemicals that may contribute to common adverse health outcomes." According to the commenter "it is critical that EPA incorporate information on non-chemical stressors in this cumulative assessment" and EPA should "issue orders for data needed to complete such assessments." The commenter also provided a list of endpoints to be considered for a cumulative evaluation of phthalates and chlorinated solvents. Similarly, a commenter (EPA-HQ-OPPT-2019-0131-0023) called for conducting a cumulative risk assessment of a phthalates category formed by the five phthalates candidates for High-Priority and the two phthalates for which industry has requested risk evaluations since "the seven phthalates merit treatment as a category because they are similar in molecular structure, toxicity, use and exposure." Another commenter (EPA-HQ-OPPT-2018-0465-0018) suggested that DIDP and DINP, as well as that Di-n-octyl phthalate (DnOP), should be added and "assessed along with the other five (or seven) phthalates." The same commenter (EPA-HQ-OPPT-2018-0465-0018) also indicated that the two sets of isomers: o-dichlorobenzene and p-dichlorobenzene, and 1,1-dichloroethane and 1,2-dichloroentaneshould be subject to aggregate and cumulative risk evaluation. An additional commenter

(EPA-HQ-OPPT-2019-0131-0016) noted "that to fulfill the intent of Congress, EPA must evaluate true risk of a chemical in commerce, and to consider aggregate and cumulative exposures."

*Comment*: A commenter (EPA-HQ-OPPT-2018-0465-0018) raised concerns with the implementation of an out-of-sync process for solicitation of public comment and conduct of the SACC scientific peer review, "depriving the peer reviewers of the ability to consider useful and robust feedback from the interested stakeholder community."

*Response: EPA appreciates the suggestions on information sources that EPA should use in the risk evaluation process. EPA determined that the 20 chemical substances were suitable candidates for the High-Priority designation based on review of reasonably available information, including relevant information received from the public and other information, as appropriate, as cited in the proposed designation documents. The reasonably available information was reviewed against the criteria and considerations set forth in 40 CFR 702.9 for a finding that each substance may present an unreasonable risk. While EPA appreciates the suggestions on specific information sources that EPA should avoid in its prioritization process, the Agency does not believe it would be appropriate to limit its analysis to certain specific data sources. EPA expects to consider the reasonably available information that is consistent with 15 U.S.C. 2625(k) in conducting its review, including information identified by commenters.*

*EPA agrees with commenters that EPA should thoroughly understand conditions of use as part of the risk evaluation process for each chemical. EPA will consider information submitted by such commenters that pertains to risk evaluation during the scoping and analysis phase of the TSCA risk evaluations for any High-Priority Substances, including information on conditions of use when developing exposure scenarios for the respective chemicals. Also note that EPA will conduct a comprehensive search of the reasonably available information about the human health and environmental hazards as well as environmental exposures and exposures to the general population and to consumers, workers and other potentially exposed susceptible subpopulations for each of the 20 High-Priority Substances. This comprehensive search is part of the systematic review process supporting the development of the risk evaluation. EPA will describe the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations that EPA expects to consider in each risk evaluation during the scoping phase of the respective TSCA risk evaluations.*

*EPA also appreciates the comments regarding improvements to the risk evaluation process and continues to implement the requirements of the "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" (40 CFR Part 702), including addressing comments from the peer reviewers and the public, as well as complying with the recent court decision regarding legacy uses and associated disposal.*

*However, please note that the provision of TSCA addressing aggregate exposures does not require EPA to conduct cumulative risk evaluations; it requires EPA to describe whether aggregate or sentinel exposure were considered, and the basis for that consideration. TSCA section 6(b)(4)(F)(ii).*
*In the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (82 FR 33753-33764), EPA agreed that the consideration of alternatives is most appropriately considered as part of any risk management rule.*

<u>Use of Existing Agency Assessments</u>

*Comments:* Several commenters (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023, EPA-HQ-OPPT-2019-0131-0010) suggested that the risk evaluation for formaldehyde under TSCA should be based on its draft IRIS assessment and this assessment should be released for public comment and peer review. One commenter (EPA-HQ-OPPT-2019-0131-0009) indicated "Formaldehyde is a chemical of high concern. It has been linked to several types of cancer and other adverse health effects and has multiple uses with the potential for widespread consumer and worker exposure." Similarly, a commenter (EPA-HQ-OPPT-2019-0131-0010) stated that "EPA needs to immediately release the recently updated IRIS assessment for public comment and NAS review. A 2019 report from the Government Accountability Office raised concerns about EPA leadership's unexplained directive to stop the release of the formaldehyde assessment. EPA must release the assessment so that the TSCA office can directly utilize the extensive work already done by NAS and IRIS scientists." Another commenter (EPA-HQ-OPPT-2019-0131-0011/EPA-HQ-OPPT-2019-0131-0019), stated that "[a]ny future risk evaluation of formaldehyde under TSCA must include its carcinogenicity. In addition, IRIS should be allowed to complete its revised human health hazard assessment of formaldehyde and EPA OPPT should integrate the results of a finalized IRIS assessment in any future risk evaluation of formaldehyde." The commenter (EPA-HQ-OPPT-2019-0131-0019) further elaborated on the health hazards of formaldehyde, which were acknowledged in the recent EPA rulemaking of composite wood products, the carcinogenicity of formaldehyde, and recent studies that support the relationship between formaldehyde and leukemia. The commenter (EPA-HQ-OPPT-2019-0131-0019) also calls for the completion of the IRIS revised human health hazard assessment of formaldehyde. Another commenter (EPA-HQ-OPPT-2018-0465-0018) stated the IRIS draft hazard assessment "should be utilized, with minimal or no alteration, as the hazard component of the TSCA risk evaluation".

*Comment:* Another commenter (EPA-HQ-OPPT-2018-0462-0006/EPA-HQ-OPPT-2018-0462-0017) offered that EPA utilize information previously gathered for TBBPA as an initial starting point (2015 Work Plan Chemical Problem Formulation and Initial Assessment), to focus the prioritization review. The commenter stated that if EPA moves forward with a risk evaluation, it should focus its review on the most relevant exposure scenarios and on the parent chemical and not metabolites or degradation products. The commenter (EPA-HQ-OPPT-2018-0462-0017) further recommends using international assessments as reference, focusing on the main TBBPA use in printed circuit boards or laminates, and offered a description of the epoxy resin creation to laminate fabrication processes. The commenter (EPA-HQ-OPPT-2018-0462-0017) also requested clarification of EPA's analysis of general population exposure and welcomed an opportunity to discuss their peer reviewed research.

*Response: EPA will provide details on how the body of scientific information, such as that included in IRIS assessments and previous problem formulations, will be considered in the risk evaluation process. These details will be incorporated into the supplemental documentation on systematic review that will be published for the High-Priority Substances.*

*The focus of the TBBPA's risk evaluation will be discussed during the scoping phase of risk evaluation. EPA typically considers the role of the parent compound, its metabolites and/or degradation products during the risk evaluation of a chemical substance.*

<u>Future Data Gathering</u>

*Comment:* Several commenters (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023, EPA-HQ-OPPT-2019-0131-0010, EPA-HQ-OPPT-2019-0131-0011/EPA-HQ-OPPT-2019-0131-0019, e.g. EPA-HQ-OPPT-2018-0421-0013) suggested that the Agency assess the quality and adequacy of available data, identify significant information gaps on hazards or exposures, and, if necessary, employ

testing and information collection authorities in TSCA sections 4 and 8, respectively. One commenter (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023) further called for EPA to establish a systematic process to obtain health and safety studies and exposure data, including using TSCA section 8(d) to obtain unpublished health and safety studies and expanding reporting under the Chemical Data Reporting (CDR) rule. A commenter (EPA-HQ-OPPT-2019-0131-0019) indicated that EPA must use its authorities under TSCA sections 4 and 8 to obtain information that it "can reasonable generate, obtain, and synthesize" since it is part of the definition of "reasonably available" information in the prioritization rule and in the risk evaluation rule. Similarly, another comment (EPA-HQ-OPPT-2019-0131-0009/EPA-HQ-OPPT-2019-0131-0023) indicated that EPA must use its section 4 authority so that the "upcoming evaluations are based on all reasonably available data on hazard and exposure." The commenter (EPA-HQ-OPPT-2019-0131-0023) indicated that TSCA section 4 authorities should include health and environmental effects testing, monitoring of workplace exposure levels, environmental releases and presence in environmental media. The commenter (EPA-HQ-OPPT-2019-0131-0019) pointed out how rules under section 8 can provide current health and safety studies or additional information beyond the (CDR) rule, and TSCA section 4 rules can fill any information gaps. Furthermore, the commenter indicated that relying on voluntary request for information will result in limited, biased, inaccurate, or incomplete information on the chemicals. One commenter (e.g. EPA-HQ-OPPT-2018-0421-0013) called for data gathering "with particular emphasis on potentially exposed and susceptible subpopulations, as TSCA requires" and recommended gathering information from "manufacturers, processors, storage facilities, recyclers, and other handlers" of the High-Priority chemicals. The commenter (e.g. EPA-HQ-OPPT-2018-0421-0013) also called for EPA to add all High-Priority chemicals to the Toxic Release Inventory and seek information directly from communities.

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0005/EPA-HQ-OPPT-2019-0131-0021) welcomed "EPA's statement that, in the absence of measured data on chemicals being evaluated, it may use new approach methods that can reduce vertebrate testing to obtain relevant data" or the use of physical chemical properties of the chemicals. The commenter (EPA-HQ-OPPT-2019-0131-0021) also indicated that they expect scoping documents to indicate if EPA determines that there is a need to develop new information, and such finding will be subject to public comment. In addition, the commenter (EPA-HQ-OPPT-2019-0131-0021) called for EPA to "remind anyone developing information for submission on a voluntary basis that they must first attempt to develop the information by means of an alternative test method or strategy."

*Response: EPA opened dockets for each of the 2014 TSCA Work Plan chemicals and an additional general docket to provide the public with a venue for submitting use, hazard, and exposure information on these chemicals (Federal Register Notice announcing the availability of the "Working Approach for Identifying Potential Candidate Chemicals for Prioritization" (83 FR 50366, October 5, 2018). This allowed for public comment on these chemicals, including submission of data that could be used by the Agency in the risk evaluation process. EPA had sufficient information to complete the prioritization assessment and make final priority designations, and may use information collection authorities for risk evaluation, if needed.*

*At the initiation of the risk evaluation process for each of the High-Priority Substances, EPA will 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. For any data needs identified through the process, EPA may use the Agency's TSCA authorities under sections 4, 8 or 11, as appropriate.*

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0010) indicated that "EPA should not use 'Application of systematic review in TSCA risk evaluations' because it is inconsistent with empirically based methods, and the data quality criteria are arbitrary and not science-based." The commenter (EPA-HQ-OPPT-2019-0131-0020) also indicated that in the risk evaluations of the 20 chemicals designated as High-Priority "EPA must address the comments from the Science Advisory Committee on Chemicals (SACC)" on previous draft risk assessments "through changes to its systematic review process." The commenter further stated that "the TSCA systematic review method should not be used, as it is not peer-reviewed or validated." Another commenter (EPA-HQ-OPPT-2019-0131-0016) noted that the criteria used by EPA in the systematic review is "not conducive to the inclusion of reliable and valid tribal data." Similarly, another commenter (EPA-HQ-OPPT-2019-0131-0023) stated that the systematic review protocol used by EPA in its initial risk evaluations is "deeply flawed and unscientific and is compromising the quality, validity and protectiveness of these evaluations" and should instead use a methodology endorsed by the National Academy of Sciences and other peer review bodies. Another commenter (EPA-HQ-OPPT-2018-0465-0018) indicated that the "flawed, non-peer-reviewed 'TSCA systematic review'" excludes evidence and doesn't allow to "reach credible, scientifically supported conclusions," and recommends using the IRIS systematic review process for evaluation of chemical risks under TSCA.

*Response: While it is outside the scope of the prioritization process or these final designations, EPA appreciates the feedback regarding systematic review and will continue to address peer reviewers' and public comments to ensure that the risk evaluations fulfill TSCA sections 26(h) and 26(i) requirements. In addition, the Agency plans to obtain peer review input from the National Academies of Sciences, Engineering, and Medicine to strengthen the systematic review process and methods described in the Application of Systematic Review in TSCA Risk Evaluations document.*

<u>Adherence to Warning Labels and Personal Protective Equipment</u>

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0011/EPA-HQ-OPPT-2019-0131-0019) stated that EPA "should account for, and acquire information needed to accurately evaluate, real world occupational and consumer exposures" and "not inaccurately assume that people comply with all warning labels and always use personal protective equipment (PPE)." EPA should adhere to the hierarchy of controls to limit workplace exposures and should collect or require the development of data to assess the actual extent of use and exposure reduction resulting from labeling and PPE. Similarly, another commenter (EPA-HQ-OPPT-2019-0131-0023) stated that the approach used by EPA to "determine that risk to workers are not unreasonable where the assumed use of [PPE] would reduce exposures to 'acceptable' levels" "lacks any legal basis, departs from established federal workplace protection policy and practice, and is contrary to the realities of worker exposure to unsafe chemicals." The commenter further indicates that "EPA should base unreasonable risk determinations for workers on measured or estimated exposure levels in the absence of PPE." Another commenter (e.g. EPA-HQ-OPPT-2018-0421-0013 ) indicated that "if EPA expects to consider PPE usage in its risk characterization, it should seek information from employers at facilities where it knows this substances is manufactured, processed, use, disposed of, or recycled regarding the specific type of PPE that is provided (what type of glove, what type of respirator), which employees receive this PPE and which do not, what training is provided regarding proper usage and how often, procedures for respirator fit-testing, and any information about exposure notwithstanding PPE use." And another commenter (EPA-HQ-OPPT-2018-0465-0018) raised concerns with making no unreasonable risk determinations for workers based on the assumption of use of PPE and excluding high-end exposures.

*Comment*: A commenter (EPA-HQ-OPPT-2019-0131-0025) provided an example of exposure controls and personal protection required for a chemical and information about the use of the candidate High-Priority chemicals in vehicles.

*Response: The Agency appreciates this feedback regarding consideration in the risk evaluations of worker protection practices such as the use of personal protective equipment (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. When appropriate, in the risk evaluation, EPA will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-specific basis for a given chemical ("EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA"* [ HYPERLINK "https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/response-comments-issues-impacting-first-10-chemicals" ]*). Similarly, for consumers, in the risk evaluation the Agency will use exposure scenarios that assume real-world consumer use of chemicals, which does not assume reliable use of PPE. The effect of labeling to address unreasonable risk will be considered during the development of risk management actions.*

Applicability of Risk Evaluation Fees

*Comment:* Two commenters (EPA-HQ-OPPT-2019-0131-0007, EPA-HQ-OPPT-2019-0131-0014) raised concerns about TSCA section 26 risk evaluation fees that might apply to chemical substances if present in "articles, components or replacement parts" or as impurities. One of those commenters (EPA-HQ-OPPT-2019-0131-0007) further requested an exemption from such fees for "companies that purchase articles or components that will then be assembled into a complex durable good" or "in lieu of an exemption, … a clear cost sharing guidance that recognizes the relative volume of the chemical contributed by each responsible company." The other commenter (EPA-HQ-OPPT-2019-0131-0014) is concerned that it will have to participate in a consortium and pay a fee for the formulations containing these impurities.

*Response: The Agency notes that risk evaluation fees apply to chemical manufacturers (including importers). If an importer is importing articles, components, or replacement parts, then they would be subject to the fee requirements. Similarly, manufacture (including import) of a chemical substance as an impurity is subject to a TSCA fee. EPA reiterates that risk evaluation fees apply to chemical manufacturers (including importers) once the chemicals are listed as High-Priority Substances and are under risk evaluation, and the fees do not apply during prioritization. There is an opportunity for companies to certify that they have ceased manufacture activities and – as a result – avoid paying fees (see 40 CFR 700.45(b)(5)-(6)); however, that window has closed for the chemical substances undergoing prioritization.*

Consideration of Downstream Users

*Comment:* One commenter (EPA-HQ-OPPT-2019-0131-0012) asked EPA to consider downstream users and their "unique stake and perspective when implementing TSCA" due to their likely interaction with consumers and retailers, as opposed to chemical manufacturers, and stressed the need for "clarity and an efficient, scientifically sound, decision-making process that addresses those substances that may present the greatest potential risk."

*Comment*: One commenter (EPA-HQ-OPPT-2019-0131-0025) "urge[d] EPA to justify their low risk and exemption determinations in as robust and clear a manner as possible to ensure regulatory certainty and an even playing field across all states."

*Response: The Agency appreciates this feedback from potentially affected persons. EPA encourages interested persons to provide chemical substance information and other comments as early as possible in the process and notes that, for High-Priority Substances, the risk evaluation process includes additional opportunities for comment. Please note that exemptions and low risk determinations are outside the scope of the prioritization process or these final designations, and a final risk determination will be part of the risk evaluation process.*

**Comments Related to Risk Management**

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0017) encouraged EPA to develop a robust body of information concerning the chemical substances under consideration for regulatory action, including the conditions of use, so that a careful consideration of such information can be used to more effectively develop and implement requirements to protect health and the environment while enabling the regulated community to pursue innovation and sustainable economic development. Also, information concerning the level of effort required to develop suitable products for specialized uses will enable EPA to better understand the potential consequences that can follow from a risk evaluation.

*Comment:* A commenter (EPA-HQ-OPPT-2018-0451-0009) described how "[106-99-0] illustrates the challenge facing industry in investing in and implementing alternatives for specific uses. The EPA report on 'Flame Retardant Alternatives for Hexabromocyclododecane (HBCD)' published in 2014 recommended a butadiene styrene brominated copolymer (CASRN 1195978-93-8). If this guidance had been acted upon, there would now be potential for applications to be adversely impacted by restrictions to 1,3-butadiene."

*Comment:* A commenter (EPA-HQ-OPPT-2019-0131-0007/EPA-HQ-OPPT-2019-0131-0025) raised concerns regarding the potential regulation of automotive articles and components and cited "very real and significant impact on our ability to produce and maintain automobiles that meet all federal, state and local safety requirements." As EPA "moves forward from the prioritization stage to the risk evaluation phase," the commenter requested "clarity for how and when in the process it will make determinations about "articles" relative to identified conditions of use," and how EPA will interpret and implement TSCA section 6(c). The commenter also raised similar concerns regarding replacement parts and indicated that "replacement parts typically do not present the same exposure risks as bulk chemicals or formulated products." The commenter requested EPA to "develop and publish for comments its policy for implementation of TSCA section 6(c)(2)(D) before the risk evaluation of any selected high priority chemicals begins." The commenter (EPA-HQ-OPPT-2019-0131-0025) also provided examples of how EPA has addressed regulatory actions regarding articles (e.g., CDR, PBT proposed rule). Similarly, another commenter (EPA-HQ-OPPT-2019-0131-0022) asked EPA to "keep in mind the requirements of TSCA section 6(c)(2)(D)(i) regarding the application of risk management measures to replacement parts for complex durable goods, such as automobiles" and "obligations with respect to applying risk management rules to substances in articles, such as parts for automobiles."

*Comments:* One commenter (e.g., EPA-HQ-OPPT-2018-0421-0006) identified a variety of uses in the aerospace industry for most of the candidates for proposed designation as High-Priority Substances and stated if such substances are "restricted or unavailable, it may have serious implications to the aerospace industry and its customers. If [such substances] cannot be used, the industry would need sufficient time to conduct research to reformulate or develop a product with equivalent performance and characteristics. Aerospace products are extremely complex and a qualified drop-in substitution with identical or superior performance is not always guaranteed or readily available."

*Response: The Agency appreciates this feedback from potentially affected persons. Please note that the final designation of a chemical substance as a High-Priority Substance is not a finding of unreasonable risk. Rather, it initiates the risk evaluation process. 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.*

*In the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (82 FR 33753-33764), EPA agreed that the consideration of alternatives is most appropriately considered as part of any risk management rule.*

*EPA notes that TSCA section 6(c)(2)(D) (replacement parts) and (E) (articles) applies to risk management, not prioritization. The chemical must first be designated as a High-Priority Substance and, if during the risk evaluation process unreasonable risk is identified, 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 following their final designations, and, if needed, will follow TSCA section 6(c)(2)(D)-(E) during any risk management phase.*