

PRE-PUBLICATION NOTICE

On Friday, December 20, 2019, Andrew R. Wheeler, the EPA Administrator, signed the following document:

Action: Notice.

Title: High-Priority Substance Designations under the Toxic Substances Control Act (TSCA) and Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability

FRL #: 10003-15

Docket ID #: EPA-HQ-OPPT-2019-0131

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2019-0131; FRL-10003-15]

**High-Priority Substance Designations under the Toxic Substances Control Act (TSCA) and
Initiation of Risk Evaluation on High-Priority Substances; Notice of Availability**

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: As required under section 6(b) of the Toxic Substances Control Act (TSCA) and implementing regulations, EPA is designating 20 chemical substances as High-Priority Substances for risk evaluation. This document identifies the final designations and Agency rationale for the chemical substances and provides instructions on how to access the chemical-specific information, analysis and basis used by EPA to support final designations for the chemical substances. A designation of a substance as a High-Priority Substance is not a finding of unreasonable risk. However, the designation of these chemical substances as high-priority substances constitutes the initiation of the risk evaluations on the substances.

DATES: The designations of High-Priority Substances for risk evaluation in this notice are effective December 20, 2019.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2019-0131, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW, Washington, DC. In addition, the docket ID numbers for the individual chemical substances designated in Unit IV. are: EPA-HQ-OPPT-2018-0451; EPA-HQ-OPPT-2018-0501; EPA-HQ-

OPPT-2018-0503; EPA-HQ-OPPT-2018-0444; EPA-HQ-OPPT-2018-0446; EPA-HQ-OPPT-2018-0426; EPA-HQ-OPPT-2018-0427; EPA-HQ-OPPT-2018-0465; EPA-HQ-OPPT-2018-0428; EPA-HQ-OPPT-2018-0504; EPA-HQ-OPPT-2018-0433; EPA-HQ-OPPT-2018-0434; EPA-HQ-OPPT-2018-0488; EPA-HQ-OPPT-2018-0438; EPA-HQ-OPPT-2018-0430; EPA-HQ-OPPT-2018-0462; EPA-HQ-OPPT-2018-0458; EPA-HQ-OPPT-2018-0459; EPA-HQ-OPPT-2018-0421; and EPA-HQ-OPPT-2018-0476. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the dockets available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT: *For technical information about the High-Priority Substances contact:* Ana Corado, Chemical Control Division, Office of Pollution Prevention and Toxics, Office of Chemical Safety and Pollution Prevention, Environmental Protection Agency (Mailcode 7408M), 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-0140; email address: corado.ana@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

I. Executive Summary

A. Does this action apply to me?

This action is directed to the public in general and may be of interest to entities that currently or may manufacture (including import) a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes

325 and 324110). The action may also be of interest to chemical processors, distributors in commerce, and users; non-governmental organizations in the environmental and public health sectors; state and local government agencies; and members of the public. Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What action is the Agency taking?

EPA is finalizing the designation 20 chemical substances as High-Priority Substances for risk evaluation pursuant to section 6(b) of TSCA, 15 U.S.C. 2605(b). This document includes a summary of comments received during the two 90-day comment periods during which the public submitted comments on EPA's initiation of prioritization (Ref. 1) and the proposed designations of High-Priority Substances for risk evaluation (Ref. 2), as well as the Agency responses to those comments (Ref. 3).

C. Why is the Agency taking this action?

TSCA section 6(b) and implementing regulations at 40 CFR part 702, subpart A require EPA to carry out a prioritization process for chemical substances that may be designated as high priority for risk evaluation. TSCA section 6(b)(2)(B) requires that EPA "ensure that risk evaluations are being conducted" on at least 20 High-Priority Substances no later than three and one-half years after the June 22, 2016 date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182). EPA is finalizing the designation of the 20 chemical substances as High-Priority Substances for risk evaluation that EPA identified as candidates for High-Priority Substance designation when EPA initiated the prioritization process on March 21, 2019 (Ref. 1). EPA provided two 90-day comment periods during which the public submitted comments on the list of candidate High-Priority Substances at the initiation of

prioritization (Ref. 1) and the documents supporting the proposed designations of High-Priority Substances for risk evaluation (Ref. 2). The two comment periods are required by TSCA section 6(b)(1)(C) and implementing regulations (40 CFR 702.7(d) and 702.9(g)).

D. What is the Agency's authority for taking this action?

This document is issued pursuant to TSCA section 6(b)(1).

II. Background

TSCA section 6(b)(1) requires EPA to prioritize chemical substances for risk evaluation. In accordance with TSCA section 6(b) and 40 CFR 702.7, on March 21, 2019 (Ref. 1) EPA initiated the prioritization process for 20 chemical substances identified as candidates for High-Priority Substance designation. On August 23, 2019, EPA proposed to designate the same 20 chemical substances as High-Priority Substances for risk evaluation (Ref. 2). That notice included a summary of the approach used by EPA to support the proposed designations, links to the proposed designation document for each of the chemical substances, and instructions on how to access the chemical-specific information, analysis and basis used by EPA to make the proposed designation for each chemical substance.

Under TSCA section 6(b)(1)(B) and implementing regulations (40 CFR 702.3), a High-Priority Substance is defined as “a chemical substance that [EPA] concludes, without consideration of costs or other nonrisk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by [EPA].”

A designation of a substance as a High-Priority Substance is not a finding of unreasonable risk. Rather, when prioritization is complete, for those chemicals designated as

High-Priority Substances, the Agency will have evidence on hazards and exposures that supports a finding that the substances may present an unreasonable risk of injury to health or the environment under the conditions of use. Final designation of a High-Priority Substance initiates the risk evaluation process (40 CFR 702.17), which culminates in a finding of whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use.

As described in the notice proposing to designate the 20 chemical substances as High-Priority Substances for risk evaluation (Ref. 2), “EPA will generally use reasonably available information to screen the candidate chemical substances against the following criteria and considerations:

- The chemical substance’s hazard and exposure potential;
- The chemical substance’s persistence and bioaccumulation;
- Potentially exposed or susceptible subpopulations;
- Storage of the chemical substance near significant sources of drinking water;
- The chemical substance’s conditions of use or significant changes in conditions of use;
- The chemical substance’s production volume or significant changes in production

volume; and

- Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance’s priority” 40 CFR 702.9(a). When selecting candidates for prioritization, the Agency also generally intends to consider (1) Agency priorities (with consideration of the priorities of other Federal agencies), (2) quantity and quality of information (to ensure that the information necessary to prioritize the substance is reasonably available), and (3) overall workload (the Agency will be mindful of the complexity associated with the assessment of the

chemical substance to ensure timely completion of prioritization and risk evaluation of each substance) (Ref. 5).

A more detailed discussion of the information, analysis and basis used to support the proposed High-Priority Substance designation can be found in Unit IV.A of the August 23, 2019 notice (Ref. 2).

As described in 40 CFR 702.9(b), in conducting the screening review during the prioritization process, EPA considered sources of reasonably available information relevant to the review criteria as outlined in the statute (TSCA section 6(b)(1)(A)) and implementing regulations (40 CFR 702.9(a)) and consistent with the scientific standards of TSCA section 26(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012), and did not consider costs or other non-risk factors in making a proposed High Priority Substance designation (see TSCA Section 6(b) and 40 CFR 702.9).

This document is intended to fulfill the requirement in TSCA section 6(b)(1)(C)(ii) that the Administrator designate 20 chemical substances as High-Priority Substances for risk evaluation after conducting a review, as required by TSCA section 6(b)(1)(A) (see also 40 CFR 702.9(a)). After considering additional information collected from the proposed designation process, described in Unit III., EPA is finalizing the High-Priority Substance designations of the same 20 chemical substance proposed for High-Priority Substance designations, consistent with the scientific standards of TSCA section 26(h) and (i). EPA did not consider costs or other non-risk factors in making the final priority designations. Instructions on how to access the chemical-specific information, analysis, and basis used by EPA to support the final designation for each chemical substance can be found in Unit IV. A general statement of the condition(s) of use that

were the primary basis for each designation is contained in Unit IV. In accordance with TSCA section 6(b)(3)(C) and 40 CFR 702.11(d), these designations will fulfill the statutory requirement to designate at least one high-priority substance upon the completion of the first 10 chemicals selected to undergo risk evaluations from the 2014 Update to the TSCA Work Plan pursuant to TSCA section 6(b)(2)(A), as announced on December 19, 2016. Pursuant to TSCA section 6(b)(3)(A), the designation of these chemical substances as High-Priority Substances constitutes the initiation of the risk evaluations on the substances.

III. Information and Comments Received

A. Overview of Public Comments

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. Under TSCA section 6(b)(1)(C)(i), EPA must “request interested persons to submit relevant information on a chemical substance that [EPA] has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided” (Ref. 1). At initiation of the prioritization process, EPA published a **Federal Register** notice identifying the chemical substances and providing a general explanation for why the Agency chose to initiate prioritization of these chemical substances. During this comment period, the public was invited to submit relevant information on the chemical substances undergoing prioritization, including, but not limited to, any information that may inform the screening review conducted pursuant to 40 CFR 702.9(a). The information received was considered when developing the proposed designations for the High-Priority Substances.

(2) a second 90-day comment period following the proposed High-Priority Substance

designations of the same 20 chemical substances identified as candidates for a High-Priority Substance designation. Under TSCA section 6(b)(1)(C)(ii), EPA must “publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation” (Ref. 2). The **Federal Register** notice proposing the designations of these substances as high priority for risk evaluation identified how to access the chemical-specific information, analysis, and basis used to support the proposed designations and announced the availability of a proposed designation document for each of the chemical substance undergoing prioritization. Interested persons were invited to submit comments on EPA’s proposed designations, including additional information relevant to the chemical substances.

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.

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 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 unique comment submissions. 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 or not related to the prioritization process in general (e.g., scheduling future chemicals for prioritization, risk evaluation, risk management, and concerns about risk evaluation fees). All comments received are identified by docket ID number EPA-HQ-OPPT-2019-0131, or by docket ID numbers for the 20 individual High-Priority Substances (see Unit IV.), and available at <https://www.regulations.gov>.

EPA responded to comments related to the High-Priority Substance designations in two general ways: (1) general comments, including overarching and cross-cutting policy and process comments, received for the candidate High-Priority Substance designations; and (2) chemical-specific comments received for the candidate High-Priority Substance designations (Ref. 3). The response to comments document (Ref. 3) is included in docket ID number EPA-HQ-OPPT-2019-0131 and available at <https://www.regulations.gov>. A synopsis of comments received related to the prioritization process, and Agency responses follows. Comments received, and Agency responses on the topics of “Request to Revise the 2014 Update of the TSCA Work Plan,” “Risk Evaluation,” and “Risk Management” are included in the full response to comments document (Ref. 3).

B. Comments on Candidate High-Priority Designations

i. Overall Prioritization Process

a. Agency Approach and Rationale

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. Specific concerns included how EPA would address instances where new data indicated that some Work Plan chemicals identified as high-priority candidates might not satisfy the statutory criteria, including the TSCA section 26 science standards; 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); and 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.”

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 (Ref. 4), 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. EPA described its prioritization in the document, “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization” (Ref. 5). 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.

EPA considered the information submitted during the two comment periods when making its proposed and final designations, in accordance with applicable statutory and regulatory requirements. To the extent that comments from the first phase provided information on additional conditions of use of the candidate High-Priority Substances, those conditions of use were discussed in the proposed designation document 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. EPA is not revising the proposed designation documents; however, information received during the two comment periods does not need to be re-submitted and will be considered in subsequent phases of the chemical-specific risk evaluations.

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” under the conditions of use. EPA interpreted this as a requirement to consider hazard and exposure as separate factors that together inform 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.

b. Potentially Exposed or Susceptible Subpopulations

A commenter urged EPA to 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, as well as consider environmental justice concerns in the prioritization process. Another commenter 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.”

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 (Ref. 6). 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. “Potentially exposed or susceptible subpopulations” could include subpopulations with unique lifeways, such as tribes, and will be considered as part of the risk evaluation process for each of the High-Priority Substances. In addition to requirements under TSCA regarding “potentially exposed or susceptible subpopulations,” the Agency is committed to consultation and coordination with Tribes (e.g., EPA Policy on Consultation and Coordination with Indian Tribes, <https://www.epa.gov/tribal/forms/consultation-and-coordination-tribes>).

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.

c. Selection of Candidate Chemicals for Prioritization

Some commenters offered thoughts on future efforts to select candidate chemicals for prioritization, including urging EPA to allow data to drive the priority designation, to merge the high- and low-priority considerations into a singular section for potential candidates for prioritization, and to give preference in designating High-Priority Substances to the substances identified by TSCA section 6(b)(2)(D).

Generally, EPA intends to use reasonably available information in the prioritization process. EPA generally expects to provide an explanation in proposed designation documents for why it chose to initiate the process for the particular chemical substance (e.g., whether EPA views this as a potential candidate for a High- or Low-Priority Substance) (Ref. 7). This is 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.

In the **Federal Register** notice initiating the prioritization process (Ref. 1) and “A Working Approach for Identifying Potential Candidate Chemicals for Prioritization” (Ref. 5), EPA described the three factors that the Agency generally intends to consider for selecting

candidates for prioritization. These are (1) Agency priorities (with consideration of the priorities of other Federal agencies), (2) quantity and quality of information (to ensure that the information necessary to prioritize the substance is reasonably available), and (3) overall workload to inform the selection of candidates (the Agency will be mindful of the complexity associated with the assessment of the chemical substance to ensure timely completion of prioritization and risk evaluation of each substance) (Ref. 5). 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, based on scores and criteria documented in the 2014 update of the TSCA Work Plan for Chemical Assessments and the Work Plans Methods Document. 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 strives to designate as 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) (Ref. 6).

d. Stakeholder Engagement and Transparency

Several commenters supported stakeholder engagement and transparency during the prioritization process, including maintaining an open and transparent process that “encourages submission of the most relevant information,” providing “greater transparency and clarity” and “more information to ascertain what information [EPA] already has and what information is needed,” and stating 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, including placing all the

“reasonably available information” in the dockets for public review, increasing transparency about the information received during the initiation of public comment period and indicating if 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 proposed designation comment period.

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 (Ref. 1), EPA used the 2014 Update to the TSCA Work Plan for Chemical Assessments as the starting point for identifying potential candidates: (1) Agency priorities (with consideration of the priorities of other Federal agencies), (2) quantity and quality of information (to ensure that the information necessary to prioritize the substance is reasonably available), and (3) overall workload (the Agency will be mindful of the complexity associated with the assessment of the chemical substance to ensure timely completion of prioritization and risk evaluation of each substance) (Ref. 5).

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 (Ref. 7). 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 designations. 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.

e. Designation Terminology

The Agency received comments related to designation terminology, including a request to clarify the definition of what is a High-Priority Substance and that a high-priority designation indicates neither risk nor unreasonable risk, given the potential for marketplace stigmatization for a chemical substance.

The Agency is not elaborating on or modifying statutory standards for High-Priority and Low-Priority Substances (Ref. 6). The Agency believes it is appropriate to rely on the statutory standards for designating High-Priority and Low-Priority Substances. These definitions have been codified in 40 CFR 702.3 as:

High-priority substance means a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Low-priority substance means a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

However, 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 (Ref. 2). EPA has included clear language for the final designations of High-Priority Chemical Substances in that regard.

f. Timeframe for Providing Chemical Substance Information

Commenters described the challenges in 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, including a call for additional time during the comment period. Another commenter 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.”

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 nine

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 nine- to 12-month timeframe under the statute, there are two three-month comment periods (following initiation and proposed designation for the substances), for a total of six 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 (Ref. 8). 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.

Regarding the Agency's data collection authority, 40 CFR 702.9 outlines the type of information sources EPA will use to inform the screening review described in 40 CFR 702.9. For the 20 chemicals identified as candidates for High-Priority Designation, EPA initiated the prioritization process with reasonably available information necessary to complete the prioritization assessment and make final priority designations and considered additional information submitted during the two comment periods when making its proposed and final designations, in accordance with applicable statutory and regulatory requirements. In future

prioritization actions, EPA may identify data needs and may use the Agency's TSCA authority under TSCA sections 4, 8, or 11, as appropriate. EPA may also exercise these authorities for risk evaluation purposes.

g. Confidential Business Information

One commenter urged EPA to implement the requirements of TSCA section 14 when prioritizing chemical substances, urging adherence to the requirements for disclosure of certain information by the Agency and the timing for confidentiality claims and substantiations.

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.

h. International Obligations

One commenter 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.

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 (Ref. 8). 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.

i. General Support of the Prioritization Process or Proposed Designation

Several commenters supported “EPA’s selection of the substances subject to this notice for prioritization for risk evaluation under TSCA” and the pragmatic approach to initiating prioritization using the 2014 TSCA Work Plan for Chemical Assessments list and the approach to consideration of reasonably available information on exposure potential. Other commenters 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” and that the proposed chemicals meet the High-Priority Substance definition.

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

j. Designation Conclusions for Specific Chemicals

EPA received various comments related to its conclusions for designating the High-Priority Substances, including trans-1,2-dichloroethylene, ethylene dibromide, Di-ethylhexyl phthalate (DEHP), formaldehyde, and 1,3,4,6,7,8-Hexahydro-4,6,6,7,8,8-hexamethylcyclopenta [g]-2-benzopyran (HHCB).

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 because of a potential hazard and a potential route of exposure under the conditions of use, 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 comments related to specific candidate High-Priority Substances, additional responses are included in the Agency's full response to comments document (Ref. 3).

ii. Review Process for Priority Designation

a. Types of Information Considered for Prioritization

Commenters urged the Agency to consider a variety of information sources and to outline the types and quality of data required when listing a chemical for 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. In particular, several commenters called on the Agency to rely on reasonably available information and strive to use the best available science; to provide notice, specifications, and transparency should new data be required to be developed; and to rely on manufacturer-conducted studies "only if it has access to and independently evaluates all available underlying data and discloses the full studies to the public without material redaction as required by section 14(b) of TSCA" and industry-generated summaries that "faithfully reflect the study findings."

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" (Ref. 5), 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 (Ref. 1).

For the 20 chemicals identified as candidates for High-Priority Designation, EPA initiated the prioritization process with reasonably available information to complete the prioritization assessment and make final priority designations and considered additional information submitted during the two comment periods when making its proposed and final designations, in accordance with applicable statutory and regulatory requirements. In future prioritization actions, EPA may identify data needs and may use the Agency's authority under TSCA sections 4, 8 or 11, as appropriate. EPA may also exercise these authorities for risk evaluation purposes. Human health and environmental hazards, as well as environmental

exposures and human exposures including potentially exposed or susceptible subpopulations, will be further considered development of the TSCA scope documents for all 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.

b. Agency Efforts to Describe Data Needs

Commenters urged EPA to “continue explicitly outlining the types and quality of data required when listing a chemical for the prioritization process” and to provide such information from the outset so that stakeholders may contribute information sooner rather than later. Another commenter cited the data supporting the EPA’s chemical prioritization process in stating 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” and that access was lacking to adequate data to understand EPA’s rationale in order to comment on this process in a meaningful way.

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” (Ref. 5) 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 a 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.

c. Identification of Conditions of Use and Persistence/Bioaccumulation for Prioritization Purposes

One commenter supported the comprehensive identification of the conditions of use in commerce for chemicals during prioritization and 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 recommended that EPA 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.” Conversely, another commenter indicated that EPA could designate a chemical substance as High-Priority for risk evaluation based on only a few conditions of use. Other commenters offered specific suggestions for EPA’s consideration of conditions of use, including: 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 well as a similar exemption for replacement parts; clarifying about the conditions of use on which a chemical is proposed as a High-Priority Substance and whether uses “surrounding” pesticides, food additives, drugs or cosmetics exclude them from the TSCA definition of a chemical substance; and consulting with downstream users to complement the information and to engage stakeholders to develop a process to improve the understanding of conditions of use. A commenter 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 commenter 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.

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 Priority Substances (see Unit IV.). 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.

EPA identified non-TSCA uses that were reported or known to EPA in the proposed designation documents to provide interested persons with a comprehensive description of the uses of the individual chemical substances undergoing prioritization. However, in the scope documents for each High-Priority Substance, EPA will present the conditions of use covered under TSCA that EPA expects to consider in the risk evaluation.

Designation as a High-Priority Substance is not a finding of unreasonable risk; rather, a final designation as a High-Priority Substance initiates the risk evaluation for such chemical substance. Furthermore, during the risk evaluation process, EPA will determine whether or not the chemical substance presents an unreasonable risk of injury 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 is also clarifying that the prioritization process did not include an update of the 2014 Update to the TSCA Work Plan for Chemical Assessments.

d. Reasonably Available Information for Prioritization

A commenter called upon the Agency to define “sufficiency of information” and clarify

how the Agency would treat exposure data gaps before initiating the prioritization process to “help industry submit necessary information during the prioritization process.” Similarly, other commenters stated that a lack of information should not lead to an assumption that a potential hazard or a route of exposure is absent and offered suggestions on minimum amounts and/or specific kinds of data EPA would need to make determinations for developmental toxicity, reproductive toxicity, carcinogenicity, and adverse endocrine effects.

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 (Ref. 6). For the 20 chemicals identified as candidates for High-Priority Designation, EPA initiated the prioritization process with reasonably available information necessary to complete the prioritization assessment and make final priority designations and considered additional information submitted during the two comment periods when making its proposed and final designations, in accordance with applicable statutory and regulatory requirements. In future prioritization actions, EPA may identify data needs and may use the Agency’s authority under TSCA sections 4, 8 or 11, as appropriate. EPA may also exercise these authorities for risk evaluation purposes. Furthermore, EPA notes that section 4(a)(2)(1)(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.”

e. Storage Near Significant Sources of Drinking Water

One commenter 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. Another commenter

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. Another commenter 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."

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 (Ref. 6). 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 [Clean Water Act] (40 CFR 401.15). In addition, EPA considered the consolidated list of chemical substances subject to reporting requirements under [the Emergency Planning and Community Right-to-Know Act] (Section 302 Extremely Hazardous Substances and Section 313 Toxic Chemicals), [the Comprehensive Environmental Response, Compensation, and Liability

Act] (Hazardous Substances), and [the Clean Air Act] (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 (Ref. 6). As necessary, EPA will 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” (Ref. 5), 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.”

iii. Submitted Data and Information

a. Data and Information on Hazard and Exposure Potential

A commenter 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) Registration, Evaluation, Authorisation and Restriction of Chemicals registration and evaluation information. The commenter highlighted the dermal test data for p-dichlorobenzene, 1,2-dichlorobenzene, and 1,2-dichloropropane. Other commenters submitted chemical-specific information for: 4,4'-(1-Methylethylidene)bis[2, 6-dibromophenol] (TBBPA); [d]ibutyl phthalate (DBP); HHCB; formaldehyde; Butyl benzyl phthalate (BBP) - 1,2-Benzene- dicarboxylic acid, 1- butyl 2(phenylmethyl) ester; phthalic anhydride; 1,2-dichloroethane; and 1,3-butadiene. With respect to comments related to specific candidate High-Priority Substances, additional

information submitted is included in the Agency's full response to comments document (Ref. 3).

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. While EPA is not revising the proposed designation documents, all information received will be considered in the chemical-specific risk evaluation process. 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 Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (Ref. 7), EPA agreed that the consideration of alternatives is most appropriately considered as part of any risk management rule.

b. Data and Information on Potentially Exposed or Susceptible Subpopulations

A commenter 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.” Another commenter supported EPA’s high-priority designation of 1,3-butadiene and also supports designating firefighters and emergency medical personnel as susceptible populations, citing classification of 1,3-butadiene as carcinogenic to humans. Another commenter provided technical reports for some of the proposed High-Priority Substances that provide an overview of potentially exposed or susceptible subpopulations for these chemicals. Another commenter provided additional information regarding uses, production volume, production sites, and impurities for phthalic anhydride, butyl benzyl phthalate, formaldehyde and 1,3-butadiene. With respect to comments related to specific candidate High-Priority Substances, additional information is included in the Agency’s full response to comments document (Ref. 3).

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.

c. Conditions of Use or Significant Changes in Conditions of Use

EPA received various comments offering information related to condition of use for candidate High-Priority Substances, including:

- Uses of phthalic anhydride, formaldehyde, 1,3-butadiene, BBP, diisobutyl phthalate, dicyclohexyl phthalate, triphenyl phosphate, 1,1,2-trichloroethane, 1,2-dichloroethane, dibutyl phthalate, diethylhexyl phthalate, and TBBPA in paints, coatings, sealants and adhesives;
- A variety of uses in the aerospace industry for most of the candidate High-Priority Substances;
- 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;”
- Use of ethylene dibromide is involved in the production of fuels; and
- Uses in automobiles for 15 of 20 of the proposed High-Priority Substances (o-dichlorobenzene, trans-1,2-DCE, 1,2-dichloroethane, 1,1,2-trichloroethane, DBP, BBP, DEHP, Di-isobutyl phthalate, Dicyclohexyl phthalate, TBBPA, Tris(2-chloroethyl) phosphate, TPP, 1,3-butadiene, formaldehyde and phthalic anhydride).

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 (Ref. 7), EPA agreed that the consideration of alternatives is most appropriately addressed as part of any risk management rule. With respect to comments related to specific candidate High-Priority Substances, the full comment and description of information submitted are included in the Agency's full response to comments document (Ref. 3).

iv. Comments Related to the Long-Term Prioritization Process

a. Future and Long-Term Process to Select Candidate Substances for Prioritization

A commenter 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 . . . , because it will set precedent for how EPA identifies, evaluates and regulates chemicals in the future.” Other commenters urged EPA to establish a predictable and routine schedule and to continue to engage stakeholders to articulate and clearly define its binning process. Another commenter requested that the Agency “finalize and release its [‘]proof of concept[’] white paper on [‘]longer term[’] prioritization soon.”

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” (Ref. 5), 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.

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) using alternative testing data 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 document, EPA also will consider federal government priorities and other interests when considering candidates for prioritization.

b. Use of Categories

One commenter indicated that in future efforts EPA may select categories of similar chemicals to prioritize together and, because of difficulties associated with categories of similar chemicals, 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.”

As stated in the preamble for the Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act Final Rule (Ref. 7), “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.”

IV. Designation as High-Priority Substances for Risk Evaluation

Based on the information provided in the August 2019 proposed designation documents, as referenced in the August 23, 2019 notice (Ref. 2), and public comments received, including information pertaining to individual chemical substances, EPA is designating the same 20

chemicals as High-Priority Substances for risk evaluation. Pursuant to 40 CFR 702.11, which states: “For High-Priority Substances, EPA generally expects to indicate which condition(s) of use were the primary basis for such designations.” For all 20 High-Priority Substances the manufacturing, processing, and use conditions of use formed the primary basis for the designation. The final High-Priority Substance designations are:

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.

The designations are based on the conclusion that each chemical substance satisfies the definition of High-Priority Substance in TSCA section 6(b)(1)(B) and 40 CFR 702.3. EPA developed a document for each substance to identify the information, analysis and basis used to support the proposed designations as a High-Priority Substance for risk evaluation. These

documents are available in the docket of each of the chemical substances with a proposed designation as a High-Priority Substance for risk evaluation. Also included in each document is an explanation of the approach used by EPA to conduct the review. Each of the documents includes an overview of the requirements in TSCA section 6(b)(1)(A) and the regulatory section addressing the following review criteria and considerations (40 CFR 702.9).

These designated High-Priority Substances will fulfill the statutory requirement to designate at least one high-priority substance upon the completion of the first 10 chemical substances selected to undergo risk evaluations from the 2014 Update to the TSCA Work Plan pursuant to TSCA section 6(b)(2)(A), as announced on December 19, 2016 (see TSCA section 6(b)(3)(C)). Pursuant to TSCA section 6(b)(3)(A), the designation of these chemical substances as High-Priority Substances constitutes the initiation of the risk evaluations on the substances.

A designation of a chemical substance as a High-Priority Substance is not a finding of unreasonable risk; rather, a final designation as a High-Priority Substance initiates the risk evaluation for the chemical substance. This is a three-year process that will culminate in a finding of whether or not the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. The chemical-specific designation documents containing the information, analysis and basis used to support the proposed designations are located in the docket for each chemical substance. As previously discussed, to the extent that comments provided information on additional conditions of use for the candidate High-Priority Substances for risk evaluation, those conditions of use were noted in the proposed designation documents for each chemical substance and will be reflected in the draft scope of the risk evaluation for each chemical substance, which will include the conceptual model and analysis plan for carrying out the evaluation. As such, EPA will not amend the proposed designation

documents. Instead, additional submitted information specific to High-Priority Substances (e.g., relevant studies and assessments) will be considered in subsequent phases of risk evaluation, including draft scope documents and draft risk evaluation documents, both of which will be subject to public comment opportunities.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket for this action includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket. For assistance in locating these referenced documents, please consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Initiation of Prioritization Under the Toxic Substances Control Act (TSCA). Notice. **Federal Register**. (84 FR 10491, March 21, 2019) (FRL-9991-06).
2. EPA. Proposed High-Priority Substance Designations Under the Toxic Substances Control Act (TSCA). **Federal Register**. (84 FR 44300, August 23, 2019) (FRL-9998-29).
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Although EPA has taken steps to ensure the accuracy of this pre-publication version, it is not the official version.

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Dated: December 20, 2019.

Andrew R. Wheeler,

Administrator.