EPA's Responses to Public Comments Received on the Scope Documents for the First Ten Chemicals for Risk Evaluation under TSCA

This response to comment document addresses cross cutting public comments that may be applicable to issues impacting all ten chemicals. The responses here represent EPA's preliminary reactions to some of the comments received, as the Agency has not reached final decisions on the approaches to the 10 risk evaluations. The Agency invites the public to provide additional comments on these Problem Formulation documents if their comments/issues have not been sufficiently addressed.

General comments

1. Many commenters asked for clarification on how the problem formulations will be different than the scope documents. Commenters added that these scopes are not as robust as TSCA demands, and EPA must address these flaws in the problem formulations. EPA needs to clarify what hazards, exposures, conditions of use, and susceptible populations are being considered in the risk evaluations (0741-0059, 0741-0060). One commenter added that "it is often unclear in these scope documents whether EPA plans to include and evaluate in the risk evaluations the hazards, exposures, and susceptible populations it has identified. The commenter believes they must be included: EPA must consider the hazards, exposures, and susceptible populations it has identified.

   Response: EPA agrees that TSCA requires that scope documents include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. EPA believes the scope documents did that, although without the level of specificity EPA expects for future risk evaluations. As explained in each of the scope documents,

   "To the extent practicable, EPA has aligned this scope document with the approach set forth in the risk evaluation process rule; however, the scope documents for the first 10 chemicals in the risk evaluation process differ from the scope documents that EPA anticipates publishing in the future. Time constraints have resulted in scope documents for the first 10 chemicals that are not as refined or specific as future scope documents are anticipated to be.

   Because there was insufficient time for EPA to provide an opportunity for comment on a draft of this scope document, as it intends to do for future scope documents, EPA will publish and take public comment on a Problem Formulation document which will refine the current scope, as an additional interim step, prior to publication of the draft risk evaluation for [chemical name]."

   EPA has published the Problem Formulation documents which refine these 10 scope documents. The conceptual models and analysis plans in the problem formulation documents more clearly identify the hazards, exposures, conditions of use and potentially exposed or susceptible subpopulations the Administrator expects to consider in risk evaluations for the first ten chemicals. Additional specificity around some of these general components (e.g., particular exposure parameters, points of departure for hazards, susceptible subpopulations based on greater susceptibility) of a risk evaluation cannot be provided until data and models are reviewed and analyses conducted. These activities and further analyses occur during the Analysis Phase of risk evaluation and will be presented in the Draft Risk Evaluation.

Conditions of Use

2. EPA received a number of comments regarding the conditions of use. Commenters urged EPA to consider the chemical substance as a whole and therefore to consider all conditions of use, and that EPA does not have discretion to ignore certain uses (0741-0059, 0735-0052), including de minimis uses (0741-0061). Other commenters added that EPA should consider reasonably foreseeable uses like accidents, misuses, and off-label uses, whole lifecycle of the chemical including legacy, and non-TSCA uses (0741-0061, 0741-0062, 0741-0056, 0741-0029). One commenter specifically questioned the exclusion of accidents, stating that the risk of accidental releases and exposures is very real and certainly "reasonably foreseen" in many respects, and EPA has authority to mandate steps to reduce those risks (0741-0059).

   Specifically, regarding legacy uses, two commenters added that legacy uses should be considered (0735-0052) (0741-0057), and others noted that there are six chemicals that contribute to ongoing exposure and risk as a result of historical manufacturing and processing activities that have been discontinued. These commenters stated that ongoing use and disposal of chemical products that are no longer being manufactured fall within the TSCA definition of "conditions of use" and must be included in problem formulations and assessed in risk evaluations (0741-0060, 0741-0062). Additionally, one commenter added that by-product or contaminant uses should also be added (0741-0057).

   Response: As discussed at length in the preamble to the final risk evaluation rule, based on legislative history, statutory structure and language, and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. EPA does not generally intend to include intentional misuses (e.g., inhalant abuse), as a ''known'' or ''reasonably foreseen'' activity in a chemical substance's risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that ''the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals.'' See, for example Senate Report 114–67, page 7. Similarly, EPA interprets the mandates under section 6(a)–(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), and consequently does not generally intend to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal.

   EPA further explained that it may, on a case-by case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. This includes uses that EPA has sufficient basis to conclude would present only ''de minimis'' exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. EPA may determine that there are appropriate regulatory safeguards in place for a particular use or that a particular use is de minimis, and that these uses can be excluded from further assessment as part of the risk evaluation. Finally, EPA also identified certain exposure pathways that are under the jurisdiction of regulatory programs and associated analytical processes carried out under other EPA-administered environmental

statutes and which EPA does not expect to include in the risk evaluation. See, 82 Fed Reg at 33729-33730 for further details on EPA's reasoning.

EPA also indicated in the preamble to the Risk Evaluation rule, and again in the chemical scope documents, that it intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. EPA went on to explain that there may be several different technical and policy perspectives in which to consider evaluating the risks of impurities, including to evaluate the potential risks within the scope of the risk evaluations for the impurity itself, within the scope of the risk evaluation for the separate chemical substances that bear the impurity, and not including the impurity within any risk evaluation where EPA has a basis to foresee that the risk from the impurity would be *de minimis* or otherwise insignificant.

The problem formulation document for each of the first 10 chemicals has been refined based on comments and input on the scope documents. The problem formulation more clearly presents what conditions of use and associated exposure pathways will be evaluated in the risk evaluation and provides rationales for EPA's decisions.

Systematic Review

3. Two commenters request that the Agency conduct systematic review to identify the hazard as these methods will strengthen and increase transparency. Specifically, 0741-0052 stated that EPA should conduct hazard identification by following systematic review processes that integrate animal, human, and mechanistic evidence and that EPA should heed the NAS recommendation to conduct risk evaluations by identifying any existing systematic reviews for a chemical substance, determining if the reviews are of high quality, and for those that are, building upon the reviews by incorporating any more recent studies that may have become available since the review was conducted (0741-0052). Another commenter provided a number of ways to improve the Agency's literature search and systematic review strategies to strengthen its evaluations and increase transparency (0741-0057).

   Response: As stated in the Risk Evaluation rule, EPA believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. EPA agrees that there are universal components of systematic review that EPA intends to apply in conducting risk evaluations. EPA has also concluded it would be premature to codify specific systematic review methods and criteria since these may change as the Agency gains more experience conducting TSCA risk evaluations.

   Along with the problem formulation documents, EPA is publishing a supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*, which contains details about the systematic review process and the evaluation strategy for assessing data quality that OPPT plans to use for these first ten chemical risk evaluations. Integrating systematic review principles into the TSCA risk evaluation process is critical to develop transparent, reproducible and scientifically credible risk evaluations.

EPA/OPPT plans to implement a structured process of identifying, evaluating and integrating evidence for both the hazard and exposure assessments developed during the TSCA risk evaluation process. The systematic review process will use existing assessments as a starting point to identify relevant references and supplement these with any more recent information. It is expected that new approaches and/or methods will be developed to address specific assessment needs for the relatively large and diverse chemical space under TSCA. Thus, EPA/OPPT expects to document the progress of implementing systematic review in the draft risk evaluations and through revisions of the *Application of Systematic Review in TSCA Risk Evaluations* document, and publication of supplemental documents.

Exposure

4. A number of commenters provided input regarding how the Agency will assess chemical exposures, specifically with regard to engineering controls. EPA should not rely on labeling and PPE as a basis to assume low or no exposure, given the major real-world limitations of these measures. EPA should account for such real-world limitations of PPE in the risk evaluations by either collecting or requiring the development of empirical data, or, in their absence, using worst-case assumptions to assess the extent of exposure reduction resulting from labeling and PPE. Reliance on such data clearly constitutes best available science (a requirement under TSCA § 26), and EPA has clear authority to collect or require the development of such data under § 4(b)(2)(A). (0741-0059, 0741-0062, 0741-0029, 0741-0057). Another commenter added that, in evaluating workplace risks, EPA should recognize and account for the uneven use and effectiveness of engineering controls, labeling and personal protective equipment in preventing occupational exposure and determine risks to workers in situations where these measures are not in place or ineffective. The problem formulation documents should explicitly recognize that industrial hygiene controls do not necessarily provide reliable and effective protection from exposure and that the adequacy of these controls needs to be examined on a case-by-case basis in the context of the specific establishments where the chemical is used, the makeup of the worker population in these establishments and the diligence of employers in implementing workplace controls (0741-0060).

   Response: OPPT's approach for developing exposure assessments for workers is to use best available information to construct realistic exposure scenarios based on data and information regarding real-world use of chemicals. When appropriate, in the risk evaluation, OPPT will use exposure scenarios both with and without engineering controls and/or PPE that may be applicable to particular worker tasks on a case-by-case basis for a given chemical.

5. There were a number of comments urging EPA to assess aggregate exposures within populations in the problem formulations, and stating that failing to do so would underestimate the risk of the chemicals. (0735-0052, 0741-0057, 0741-0060, 0741-0061, 0741-0029)

   Response: The statute requires that the Agency describe whether aggregate (or sentinel) exposures were considered, see 15 USC 2605(b)(4)(F)(ii); whichever exposure assessment method is ultimately used will be accompanied by an explanation in the Risk Evaluation. In conducting an aggregate exposure assessment, EPA may also include exposures from non-TSCA uses, e.g., as part of background; whether and how to account for such exposures will be

evaluated on a case-by-case basis. EPA will consider whether to assess aggregate exposure when developing the exposure assessment during the Analysis Phase of the Risk Evaluation.

6. Two commenters asked how EPA will incorporate cumulative risk, as well as aggregate, in the first 10 risk evaluations. Commenters added, to properly apply either or both of these approaches in a risk evaluation, EPA must determine in advance what methodology it will employ and then incorporate it in the risk evaluation design in sufficient detail to describe the key data sources it will use to assess exposure and how they will be used. (0741-0060, 0741-0061)

   Response: Cumulative exposure is not required under the statute. EPA retains the discretion to conduct a cumulative assessment but has not yet determined whether to do so for any of the first 10 risk evaluations. However, EPA may ultimately determine that for a certain chemical or category a cumulative exposure assessment is appropriate for certain endpoints.

Hazard

7. One commenter asked EPA not to prejudge the absence of adverse effects for particular end-points at the scoping stage but to defer such conclusions until the systematic review phase of its risk evaluation as the law requires (0741-0060).

   One commenter expressed concern that EPA says in all the chemical scoping documents in the Section on Environmental Hazards that it expects to consider other studies, including data from alternative test methods such as computational toxicology, bioinformatics, high-throughput screening methods, read-across data, etc. Many of these alternative test methods, and particularly their application to risk assessment, are still emerging and, although promising, have serious limitations. However, if utilized prematurely or incorrectly, these tools could allow for the rapid and erroneous exoneration of harmful chemicals. These tools lack complete biological coverage, cannot presently evaluate the potential toxicity associated with chemical metabolism and absorption, and have the potential for high false negatives relative to whole animal studies (0741-0062).

   Response: EPA does not intend to prejudge any conclusions before completing the systematic review process supporting the risk evaluations. OPPT is aware of the status of alternative test methods with regard to the methodological validation, standardization and acceptance (e.g., established OCSPP or OEC Test Guideline vs. basic research approach). Regardless of the level of regulatory or international recognition, data from other studies and alternative test methods can inform risk evaluation if they are determined to be consistent with the best available science and can inform the weight of the scientific evidence. Like other, more traditional testing studies, studies conducted using non-guideline approaches or using alternative test methods will be evaluated for quality and relevance following the process described in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*. In addition, all risk evaluations will be subject to public comment and independent peer review. OPPT anticipates use of data from alternative test methods.

   TSCA section 26(h) requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific information, technical procedures, measures, methods, protocols, methodologies, or models consistent with the best available

science. TSCA section 26(i) requires EPA to make decisions under TSCA sections 4, 5, and 6 based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

8. One commenter stated that three chemicals (carbon tetrachloride, methylene chloride and 1-bromopropane) have data showing a high ozone depletion potential and that this should fall within the scope of the risk evaluation (0742-0060).

   Response: Regulation of ozone-depleting substances (ODS) falls under the jurisdiction of the Clean Air Act, administered by EPA's Office of Air and Radiation. Because ozone depletion risks are adequately assessed and effectively managed under the Clean Air Act, EPA does not expect to include ozone-depletion potential in risk evaluations for carbon tetrachloride, methylene chloride or 1-bromopropane. EPA regulations under Sections 601-607 of the Clean Air Act phase out the production and import of class I and class II ODS (https://www.epa.gov/ods-phaseout) with limited exceptions. Carbon tetrachloride is subject to these regulations, addressing its ozone-depletion risks. Furthermore, under Section 612 of the CAA, EPA's Significant New Alternatives Policy (SNAP) program reviews substitutes for ODS. New chemicals that are proposed as substitutes are reviewed in coordination with OCSPP's New Chemicals Program, and significant new uses of existing chemicals are also reviewed under the SNAP program. Various environmental and health risks of methylene chloride and 1-bromopropane (n-propyl bromide), including their ozone-depletion potential, have been evaluated for specific uses under the SNAP program.

Health Protective Defaults

9. A number of commenters urged EPA to use health-protective defaults if the agency lacks information specific to a chemical, and health-protective methods to quantify risk when characterizing risk (0741-0052, 0741-0057, 0741-0062). Specifically, for cancer, a commenter highlighted the NAS recommendation that EPA include a factor to account for human variability in response to carcinogens, as EPA's current approach inaccurately assumes that there is no variability in response. Similarly, EPA should increase or add factors that address cancer and non-cancer susceptibility during early life stages (0741-0057).

   One commenter urged EPA not to use MOE (margin of exposure) as an analysis method in the risk evaluation process, as MOE is not an estimate of risk—it is a single number that is a version of the "bright line" approach like the Reference Dose (or Reference Concentration for inhalation doses) (0741-0057).

   Response: EPA does not want to *a priori* preclude the use of any methods or data types, to allow its evaluations to change as science advances. EPA will utilize current policies, models, and screening methods, but is committed to being consistent with the best available science and weight of the scientific evidence approaches to guide the Agency in using this information. EPA recognizes the advancing science to inform risk evaluation and will not discourage the use of new methods as long as they are consistent with the standards in section 26 of TSCA. EPA also recognizes that different approaches require different types and amounts of data and will select and employ methods that are fit for purpose within the context of a particular risk evaluation. In some cases, it may be necessary to utilize default parameters in modeling and risk calculations, and to utilize conservative assumptions, whereas in other cases assumptions may be replaced with specific or specialized data. It should also be noted, in addition, their use will

be peer reviewed, and the public will have the opportunity to comment on them during the public comment periods.

EPA has utilized the MOE approach in previous risk assessments, citing its utility. However, EPA does agree with comments that there are numerous ways to characterize risk, of which MOE is just one. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. Hence, OPPT will use risk characterization approach(es) suitable for the purpose of the risk evaluation and that the best available science and data support. EPA does not agree with the commenter that the use of MOEs is never appropriate.

Confidential business information (CBI)

10. A number of commenters added comments regarding CBI. Two requested EPA require that claims of confidential business information be fully substantiated by industry and not used to conceal critical information from the public (0741-0052, 0741-0057, 0074-0059). Another added that EPA needs to take stronger steps to limit CBI treatment of critical information during the risk evaluation process so that transparency and public participation in that process are not impaired (0741-0060).

    One commenter added that the strategy for conducting literature searches appears to state that EPA excluded from the search "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information." But the information EPA has already collected about these chemicals is potentially relevant to the risks they present, even if the information is not yet publicly disclosed. This information falls squarely within EPA's definition of "reasonably available information" as "information that EPA possesses." 40 C.F.R. § 702.33. Indeed, EPA expressly stated that "[i]nformation is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14." *Id.* Since this information is reasonably available EPA must review it (0741-0059).

    Additionally, this commenter raised the question as to whether this information may not meet the new, stricter requirements and standards for nondisclosure under TSCA § 14 as amended by the Lautenberg Act. Historically EPA has failed to review CBI claims, and while the Lautenberg Act requires EPA to do so, the public has little evidence to date that EPA is complying with this new mandate. So EPA may never have reviewed the CBI claims for this information, particularly if it was submitted before passage of the Lautenberg Act (0741-0059).

    Response: TSCA requires that CBI claims must be asserted and substantiated concurrently with the submission of information, except for information that is deemed exempt under TSCA section 14(c)(2).

    The risk evaluation rule does clarify that the agency does consider CBI as "reasonably available information" and will utilize it in risk evaluations were relevant.

    The *Strategy for Conducting Literature Searches for each TSCA Scope document* described the procedure for searching the public literature which does not include searching "[d]ocuments not available to the public, including information stored within EPA's firewall that is not accessible

on the EPA webpage (e.g., TSCA submissions) [and] Confidential Business Information". However, OPPT is searching internal information it may possess as part of the process of conducting the risk evaluations. This is discussed in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

EPA will comply with TSCA section 14 review and disclosure requirements for data/information that is claimed confidential and deemed relevant for the risk evaluation.

Potentially exposed and susceptible subpopulations

11. Commenters provided feedback regarding EPA's approach to identifying "potentially exposed or susceptible subpopulations." One commenter suggested that EPA address susceptible sub-populations, following recommendations from the National Academies of Sciences (NAS) to identify susceptible sub-populations based on established extrinsic and intrinsic factors that increase vulnerability (0741-0057).

    Another commenter suggested the language provided in the scopes was general "boilerplate" descriptions of such subpopulations, adding that further particulars on the size, geographic location, demographic characteristics and exposure profile of each subpopulation EPA has identified would provide helpful assurance that the risks to that subpopulation will be characterized with the rigor that TSCA requires (0741-0060). Similarly, a commenter asked for more clarification in the problem formulation documents of those populations with greater susceptibility (0741-0059).

    Another commenter encouraged EPA to consider for every chemical review: (1) occupational exposures that are often at much higher exposure levels than the general public, both acutely and chronically, and can be concurrent with other chemical exposures at the workplace; (2) fence-line communities who also face multiple exposures to multiple chemicals and suffer from many chronic health conditions and health inequalities; (3) sensitive time periods during life, such as pregnancy and during childhood; (4) tribal communities where cultural and lifestyle considerations may result in very different exposure profiles and where there are often disproportionate adverse health outcomes; and (5) general variability in human responses. The commenter encouraged EPA to actively seek input from fence-line and other impacted communities, occupational workers at manufacturing, processing, distributing, or recycling facilities, concerned members from the public, and tribal communities and incorporate their concerns in the Agency's evaluations where appropriate." (0741-0029)

    A commenter added comments specifically regarding occupational exposure: Occupational workers exposed during the manufacture, processing, disposal, etc. of these chemicals should always be considered separately as a susceptible population. Furthermore, the consideration of exposed workers should always include the potential for pregnant women and consider both women and men of childbearing age as a vulnerable population when assessing the risk (0741-0029 and 0741-0059).

    Finally, one commenter urged the agency to seek communities' and public health experts' input as to the appropriate means to identify vulnerable and chemically overburdened populations when drafting scoping documents. The commenter also requests that EPA apply its own established principles for promoting environmental justice when determining the scope of a risk assessment (0741-0061).

Response: While EPA wholly agrees that protecting potentially exposed or susceptible subpopulations is an important part of EPA's mandate, the process for identifying the subpopulations considered in each risk evaluation will be case specific and, consistent with the directive in section 6(b)(4)(A), tailored as relevant to the risk evaluation. Furthermore, EPA will use the best available science and prevailing guidance, such as recommendations of the NAS, in defining and assessing such subpopulations.

Every risk evaluation must consider any 'potentially exposed or susceptible subpopulations' determined to be relevant to the risk evaluation under the conditions of use. However, potentially exposed or susceptible populations and subpopulations can vary depending on the chemical and conditions of use being evaluated. EPA is required by statute to consider relevant potentially exposed or susceptible subpopulations, which could include children, pregnant women, and other subpopulations as appropriate for the assessment. For example, when appropriate, EPA will include specific life-stages exposure scenarios which may be more representative of various exposures that affect children.

Likewise, if workers are determined to be a population likely to be exposed to a chemical during its conditions of use, this population would be included as a 'potentially exposed or susceptible subpopulation' and therefore considered in the risk evaluation. In fact, in the scope documents, EPA identified both workers and consumers as susceptible subpopulations on the basis that they are more exposed than the general population to chemicals and/or products that the general population does not work with or use. EPA acknowledged in the scope documents that measurement and evaluation methods for these, and potentially other, subpopulations is still being refined.

EPA welcomes information from communities and will use it to further refine risk evaluations.

To this end, EPA has already sought input from specific populations and public health experts in implementing TSCA and will continue to do so. For example, EPA has had discussions on several occasions with the National Tribal Toxics Council to receive input on tribal lifeways and exposures. OPPT and the NTTC continue to collaborate on ways to consider tribes in conducting potentially exposed or susceptible subpopulations analyses for Draft Risk Evaluations. OPPT has also had several meetings with AFL-CIO about workers as potentially exposed or susceptible subpopulations and ways in which worker exposure information could be identified and provided for use in the risk evaluation process. OPPT has also sought advice and input regarding children as a susceptible subpopulation from the Children's Health Protection Advisory Committee (CHPAC) through a meeting and recommendations addressing the formal request from EPA for guidance on how risk evaluation should address children. CHPAC's recommendations can be found here.

IRIS Assessments

12. A few commenters urged EPA to use existing IRIS assessments (0741-0061, 0741-0062). Specifically, EPA should rely on existing IRIS assessments for hazard identification, and moving forward, EPA should complete hazard identification or add additional studies only through a systematic review process, which integrates animal, human and mechanistic evidence as recommended by the recent NAS report (0741-0057). EPA does not need to revisit definitive findings in IRIS assessments since these assessments represent the Agency's authoritative, peer reviewed determinations on the health effects of the chemicals they address (0074-0060).

    Response: As discussed in the scope documents, where applicable, OPPT has used IRIS documents as a starting point for identifying key and supporting toxicity studies and initial hazard identification. However, EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. Specifically, EPA will screen information developed after the completion of any IRIS assessment and evaluate the relevant information using OPPT's structured process described in the documents *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.*

Information Gathering

13. EPA received a number of comments on information gathering.

"EPA must consider "reasonably available" information, and thus EPA must consider the information it already possesses and use its authorities under TSCA [sections] 4 and 8 to obtain additional information. The scoping documents suggest that EPA will fall far short of meeting this standard. In all of the scopes, EPA stated that it would search "readily available data and information from public sources," and "EPA encourages submission of additional existing data, such as full study reports or workplace monitoring from industry sources" (p.42). But this approach to collecting data is insufficient as a matter of law. Each scope refers to "readily available" information, but the standard under TSCA is reasonably available information. Additionally, any information that EPA can obtain under the exercise of its authorities under §§ 8(d), 8(a), and 8(c) is "reasonably available information," so EPA must exercise those authorities. EPA must identify any information gaps and use its authority under TSCA § 4 to the fullest extent possible to fill those gaps." (0741-0059).

Response: The commenter is correct, as the scope documents should refer to "reasonably available information", not "readily available". In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. Below EPA has collated a non-exhaustive list of the information activities associated with collecting reasonably available information. EPA notes that it selected the first 10 chemicals for risk evaluation based in part on its assessment that these chemicals could be assessed without the need for regulatory information collection or development.

Generate: EPA explained in the risk evaluation rulemaking that reasonably available information includes information that could be generated through testing, where that information can be generated and synthesized within the statutory timeframes and would be of sufficient value to merit the testing. As of now, EPA has not identified the need for any such testing for the first 10

chemicals. In the timeframe allotted to initiate the risk evaluation process and develop the scoping documents for the initial ten chemicals subject to risk evaluation following the 2016 amendments to TSCA, EPA consulted a variety of information sources, both internally and externally, and currently believes the information obtained through these investigations is sufficient to make the necessary determinations. As we have previously indicated (for instance, in the scope documents for the first ten chemicals), in the future prioritization (and pre-prioritization) processes, EPA will have additional time prior to risk evaluation to evaluate data landscapes and judge whether testing would be appropriate. While the timeframes for these first 10 risk evaluations have necessarily constrained EPA's ability to require testing, EPA does not currently see the need for testing to complete these risk evaluations.

Obtain: EPA conducted extensive and varied data gathering activities for each of the first 10 chemicals, including:

(1) Conducted extensive and transparent searches of public databases and sources of scientific literature, government and/or industry sector or other reports, etc. [See supplemental file, Strategy for Conducting Literature Searches, associated with each of the ten chemicals on the chemical's webpage].
(2) Searched EPA TSCA 8(e) and CBI submission holdings for data on the first ten chemicals.
(3) Consulted a variety of sources to identify conditions of use of the initial ten chemicals. These sources included information reported to EPA (including Chemical Data Reporting and the Toxics Release Inventory), literature searches, proprietary reports, trade publications, and reports developed for prior EPA and international assessments. To identify formulated products containing <chemical>, EPA searched for safety data sheets (SDS, formerly referred to as material safety data sheets (MSDS)) using internet searches, EPA Chemical and Product Categories (CPCat) data, the National Institute for Health's (NIH) Household Product Database, and other resources in which SDS could be found. Each SDS was then cross-checked with company websites to make sure that each product SDS was current. EPA also communicated with companies, industry groups, international regulatory agencies, and non-governmental organizations, to make sure the list of uses was correct, complete, and up-to-date. A preliminary list of uses was presented to the public for comment ahead of a public meeting as part of a use document for <chemical>. Those public comments as well as information from other engagements with stakeholders were integrated into this scoping document.
(4) Conducted a market analysis of conditions of use using proprietary databases and repositories.
(5) Conducted many outreach meetings with chemical manufacturers, processors, chemical users, non-governmental organizations, trade organizations, and other experts, including other State and Federal Agencies (e.g., Dept of Defense, NASA, OSHA, NIOSH, FDA and CPSC) for each of the initial ten chemicals [See Docket(s) https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten] to support development of conditions of use documents [see Dockets https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca#ten] and scope documents
(6) Published conditions of use documents, solicited public comment/input on conditions of use of the initial ten chemicals, convened a public meeting and opened dockets to receive

written public comments. See the following link for additional information: https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/risk-evaluations-existing-chemicals-under-tsca

(7) Solicited public input on Scope documents and encouraged submission of additional data/information regarding the scope for each of the initial ten chemicals
(8) Consulted existing systematic review approaches and methods to inform development of data evaluation step of systematic review under TSCA
(9) Worked with chemical manufacturers, industry associations, other federal agencies, state governments, unions, non-governmental organizations, and international regulatory partners to discuss additional data/information that would inform risk evaluations and scenarios where people could be exposed to the initial ten chemicals. As a result, EPA received additional study reports regarding hazard information, (e.g. PV29), occupational monitoring data from DoD, data from OSHA on worker exposures, and a variety of information from a wide swath or stakeholders on how chemicals are used in specific industries.
(10) Published Problem Formulation documents and solicited public input to obtain further information useful for developing the draft risk evaluation

Synthesize: EPA has synthesized reasonably available information in several phases during the risk evaluation process for the first chemicals, as follows:

(1) Developed conditions of use documents that synthesize the data/information obtained from searches and meetings with stakeholders for each the initial ten chemicals.
(2) Conducted title and abstract screening on all references obtained from the literature searches, synthesizing this information into 'on topic' and 'off topic' bins for all ten chemicals [see supplemental file, Bibliography, for each of the ten chemicals on the chemical's webpage].
(3) Developed Scope documents that synthesize conditions of use and lifecycle information for each chemical to describe the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation and link them to the plan for the analyses to be included in the risk evaluation.
(4) Synthesized existing methods/approaches to systematic review to develop the evaluation strategies to assess data/information quality as described in the supplemental document, *Application of Systematic Review in TSCA Risk Evaluations*
(5) Synthesized additional input/data/information received on scope documents in developing problem formulation documents that synthesize conditions of use and lifecycle information for each chemical to describe the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider in the risk evaluation and link them to the plan for the analyses to be included in the risk evaluation.
(6) Consulted within EPA, across major media programs, to integrate and synthesize (cross-walk) the nexus between TSCA and other major media statutes and regulatory programs (e.g., CAA, CWA, SDWA, RCRA).

EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. EPA will consider use of its

information gathering authorities under section 8 on a similar basis – i.e., considering the statutory deadlines and the value the additional information would likely have in reducing uncertainty in its fit-for-purpose evaluations. As discussed in the prioritization rulemaking, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. For these first ten risk evaluations, EPA believes that these are generally data-rich chemicals, and the use of our data gathering authority is not warranted at this time. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques). EPA will tailor its information gathering efforts as appropriate.

"Problem formulations should highlight aspects of use and exposure where available information is insufficient and request or require submission of this information by industry and other interested parties." (0741-0060)

Response: To date, EPA has gathered extensive use and exposure data for these ten chemicals and believe we have adequate use and exposure info. In fact, some additional information on uses and exposure were submitted during the comment period on the Scope documents and this information was used to refine the problem formulations. We will seek to obtain more if we find we need it.

"Absence of data does not equal no risk, and efforts to obtain data should occur immediately" (0741-0029).

Response: OPPT does not believe that absence of data equals no risk. However, when OPPT does find existing data are not adequate, OPPT will use all available authorities to fill data gaps necessary to conduct fit-for-purpose assessments. As discussed previously, due to the deadlines mandated in TSCA, information must be reasonably available within the constraints of the timeframes imposed.

"When EPA relies on prior assessments, EPA must provide a short analysis indicating why they are sufficiently reliable to ensure that EPA is not overlooking reasonably available information" (0741-0059).

Response: EPA will re-evaluate the quality of the key/supporting data/information sources used in previous assessments by applying standards and guidance under amended TSCA.

"EPA has provided no sound reasoning for relying solely on voluntary requests for information, and doing so may result in limited, biased, inaccurate, or incomplete information on the chemicals, and this does not constitute all "reasonably available" information. By contrast, If EPA acts under TSCA §§ 8(a), (c), and (d), the regulations impose some requirements that will help ensure the accuracy and completeness of the information." (0741-0059)

Response: EPA has not indicated it would rely solely on voluntary requests for information.

"EPA should use section 4, 8(a), 8(c), 11 and 26(a) to fill data gaps, as the information obtained would constitute 'reasonably available information." (0071-0061)

Response: EPA will use available authorities to fill data gaps as appropriate. However, EPA must adhere to the timeframes imposed by TSCA. In the risk evaluation rule, EPA defined reasonably available information to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. And, consistent with the risk evaluation rule preamble, EPA will consider the value of the information that would be obtained through its information collection authorities in judging whether the information is reasonably available.

Alternative Assessment

14. One commenter strongly urged EPA to conduct comprehensive alternative assessments with a priority on hazard assessment for of each of the ten chemicals under consideration. Four of the ten chemicals currently selected by EPA as priority chemicals for risk evaluation have been previously listed by EPA as "acceptable substitutes" under the Significant New Alternatives Policy (SNAP) program that reviews substitutes for ozone-depleting substances within a comparative risk framework. The need now to reevaluate these chemicals will require millions of additional taxpayer dollars for the evaluation itself, as well as potentially millions of dollars in private resources as companies move a second time to replace what EPA deems a hazardous chemical with an acceptable substitute. By using a comprehensive alternatives assessment framework that prioritizes hazard, EPA will be able to reach conclusions about each of the ten chemicals that are far less likely to result in the need for reassessment in a few years (0741-0058).

    Response: In the prioritization rule, EPA stated that an alternative assessment of substitute chemicals is more appropriate during the risk management phase.

Ongoing Section 6(a) rule makings

15. Two commenters included comments regarding the on-going section 6(a) rulemakings that may impact trichloroethylene, methylene chloride, and N-Methylpyrrolidone. One commenter specifically questions EPA's decision not to examine uses addressed by its planned 6(a) rules governing certain uses of TCE, DCM, and NMP, and furthers states that this is only justified if EPA plans to move forward with risk management rules that ban these uses and thereby eliminate the unreasonable risks previously identified for these uses. "By definition, EPA has already found these uses to be "conditions of use" as "the circumstances, as determined by the Administrator, under which a chemical substance is known to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2605(b)(4)(A), 2602(4). In addition, EPA has already found that these uses present unreasonable risks. It would be absurd for EPA to exclude these uses unless EPA has already banned these uses to eliminate the unreasonable risks and ensure that such uses no longer present any residual risk which would otherwise need to be included in the present risk evaluations for those chemicals" (0741-0059).

    Another commenter adds that EPA risk evaluations should not reassess uses of trichloroethylene (TCE), methylene chloride (MC) and N-Methylpyrrolidone (NMP) that were fully assessed in its proposed section 6(a) rules, although these exposure pathways should be included in its determinations of aggregate exposure to these chemicals (0741-0060).

Response: Although EPA indicated in the TCE, NMP and MeCl scope documents that EPA did not expect to evaluate the uses assessed in the 2014 or 2015 risk assessment in the TCE, NMP or MeCl risk evaluation, respectively, EPA has decided to evaluate these conditions of use for TCE and NMP in the risk evaluation. EPA is including these conditions of use so that they are part of EPA's determination of whether TCE and NMP presents an unreasonable risk "under the conditions of use," TSCA 6(b)(4)(A). EPA has concluded that the Agency's assessment of the potential risks from these widely used chemicals will be more robust if the potential risks from these conditions of use are evaluated by applying standards and guidance under amended TSCA. In particular, this includes ensuring the evaluations are consistent with the scientific standards in Section 26 of TSCA, the *Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act* (40 CFR Part 702) and EPA's supplemental document, *Application of Systematic Review in TSCA Risk Evaluations.* EPA also expects to consider other available hazard and exposure data to ensure that all reasonably available information is taken into consideration. It is important to note that conducting these evaluations does not preclude EPA from finalizing the proposed TCE and NMP regulation. On May 10th, 2018 EPA announced it intends to finalize the methylene chloride rulemaking proposed in January 2017. Therefore, EPA will not re-evaluate the paint stripping uses of methylene chloride and will be relying on the previous assessment.

Other

16. One commenters shared information on the "Beyond Science and Decisions" project, a risk methods compendium as a resource for regulators and scientists on key considerations for applying selected dose-response techniques for various problem formulations, with suggested techniques and resources (0741-0057).

    Response: Thank you for this comment and for the suggested resources.