

## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 702

[EPA-HQ-OPPT-2023-0496; FRL-8529-01-OCSPP]

RIN 2070-AK90

### Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)

**AGENCY:** Environmental Protection Agency (EPA).

**ACTION:** Proposed rule.

**SUMMARY:** The Environmental Protection Agency (EPA, “the Agency”) is proposing to amend the procedural framework rule for conducting risk evaluations under the Toxic Substances Control Act (TSCA). The purpose of risk evaluations under TSCA is to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or non-risk factors, including unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant to the risk evaluation by EPA, under the conditions of use. EPA has reconsidered the procedural framework rule for conducting such risk evaluations and determined that certain aspects of that framework should be revised to better align with applicable court decisions and the statutory text, to reflect the Agency’s experience implementing the risk evaluation program following enactment of the 2016 TSCA amendments, and to allow for consideration of future scientific advances in the risk evaluation process without need to further amend the Agency’s procedural rule.

**DATES:** Comments must be received on or before December 14, 2023. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before November 29, 2023.

**ADDRESSES:** Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2023-0496, through the Federal eRulemaking Portal at <https://www.regulations.gov>. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information

about dockets generally, is available at <https://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 564-4371; email address: [blair.susanna@epa.gov](mailto:blair.susanna@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](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Executive Summary

###### A. Does this action apply to me?

EPA is primarily proposing to amend procedural requirements that apply to the Agency’s activities in carrying out TSCA risk evaluations. However, EPA is also proposing certain amendments to the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted TSCA risk evaluation on a particular chemical substance. You may be potentially affected by this action if you manufacture or import chemical substances regulated under TSCA. 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. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Petroleum Refineries (NAICS code 324110);
- Chemical Manufacturing (NAICS code 325);
- Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS code 326113);
- Unlaminated Plastics Profile Shape Manufacturing (NAICS code 326121);
- Plastics Pipe and Pipe Fitting Manufacturing (NAICS code 326122);
- Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing (NAICS code 326130);
- Polystyrene Foam Product Manufacturing (NAICS code 326140);
- Urethane and Other Foam Product (except Polystyrene) Manufacturing (NAICS code 326150);
- Plastics Bottle Manufacturing (NAICS code 326160);

- Plastics Plumbing Fixture Manufacturing (NAICS code 326191);
  - All Other Plastics Product Manufacturing (NAICS code 326199);
  - Tire Manufacturing (except Retreading) (NAICS code 326211);
  - Tire Retreading (NAICS code 326212);
  - Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220);
  - Rubber Product Manufacturing for Mechanical Use (NAICS code 326291);
  - All Other Rubber Product Manufacturing (NAICS code 326299);
  - Pottery, Ceramics, and Plumbing Fixture Manufacturing (NAICS code 327110);
  - Clay Building Material and Refractories Manufacturing (NAICS code 327120);
  - Flat Glass Manufacturing (NAICS code 327211);
  - Other Pressed and Blown Glass and Glassware Manufacturing (NAICS code 327212);
  - Glass Container Manufacturing (NAICS code 327213);
  - Glass Product Manufacturing Made of Purchased Glass (NAICS code 327215);
  - Cement Manufacturing (NAICS code 327310);
  - Ready Mix Concrete Manufacturing (NAICS code 327320);
  - Concrete Block and Brick Manufacturing (NAICS code 327331);
  - Concrete Pipe Manufacturing (NAICS code 327332); and
  - Other Concrete Product Manufacturing (NAICS code 327390).
- If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

###### B. What is the Agency’s authority for taking this action?

EPA is issuing this Notice of Proposed Rulemaking (NPRM) pursuant to the authority in TSCA section 6(b)(4) (15 U.S.C. 2605(b)(4)). EPA has inherent authority to reconsider previous decisions and to revise, replace, or repeal a decision to the extent permitted by law and supported by reasoned explanation. See *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); see also *Motor Vehicle Mfrs. Assn v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). See also the discussion in Units II.A. and B.

###### C. What action is the Agency taking?

EPA is proposing to amend regulations that address how the Agency conducts risk evaluations on chemical

substances under TSCA. These changes include, but are not limited to, targeted changes to certain definitions, clarifications regarding the required scope of risk evaluations, considerations related to peer review and the Agency's implementation of the scientific standards, the approach for risk determinations on chemical substances and considerations related to unreasonable risk, and the process for revisiting a completed risk evaluation. EPA is also proposing to amend the process and requirements for manufacturers making a voluntary request for an Agency-conducted risk evaluation on a particular chemical substance. EPA is requesting public comment on all aspects of this proposal.

#### D. Why is the Agency taking this action?

As further explained in Units I., II., and III., EPA reexamined the July 20, 2017, final rule (Ref. 1) (hereinafter "2017 final rule") that established procedures and requirements for chemical risk evaluation under TSCA, in consideration of:

- The statutory text and structure and Congressional intent.
- The November 14, 2019, opinion issued by U.S. Court of Appeals for the Ninth Circuit in response to petitions for judicial review, consolidated under *Safer Chemicals, Healthy Families v. USEPA* (Ref. 2), of the 2017 final rule and related court orders.
- Executive Order 13990, *Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis* (Ref. 3).
- Lessons learned from the Agency's implementation of the risk evaluation program to date including feedback from the National Academies of Science Engineering and Medicine and scientific peer reviewers.

As a result of this reexamination, the Agency is proposing targeted amendments of the 2017 final rule.

#### E. What are the estimated incremental impacts of this action?

The incremental impacts of this action are associated with procedural requirements, as described in Unit III.K., which apply to manufacturers when manufacturers (including importers) elect to request that EPA perform a risk evaluation on a particular chemical substance. EPA has estimated the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. These estimates of burden and costs are available in the docket, and are

discussed in Unit V. and briefly summarized here (Ref. 4).

The total estimated annual burden is 166 hours and \$115,711 (per year), which is based on an estimated per request burden of 166 hours.

In addition, EPA's evaluation of the potential costs associated with this action is discussed in Unit VI.B. Since this rulemaking focuses on the activities that a manufacturer must perform, the estimated incremental costs to the public are expected to be negligible. EPA requests specific comment on the burden estimate and assumptions associated with the calculation associated with the burden (e.g., number of requests EPA expects).

#### F. What should I consider as I prepare my comments for EPA?

##### 1. Submitting CBI

Do not submit CBI to EPA through <https://www.regulations.gov> or email. If you wish to include CBI in your comment, please follow the applicable instructions at <https://www.epa.gov/dockets/commenting-epa-dockets#rules> and clearly mark the part or all of the information that you claim to be CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

##### 2. Tips for Preparing Your Comments

When preparing and submitting your comments, see the commenting tips at <https://www.epa.gov/dockets/commenting-epa-dockets.html>.

## II. Background

### A. Statutory Requirements for Risk Evaluation

TSCA section 6(b)(4) requires EPA to establish, by rule, a process to conduct risk evaluations. Specifically, EPA is directed to use this process to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use." (15 U.S.C. 2605(b)(4)(A)). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances

must undergo risk evaluation, the development of criteria for manufacturer-requested risk evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and completion of the risk evaluation. The law also requires EPA to consider reasonably available information and operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. (15 U.S.C. 2625(h) and (i)).

### B. Judicial Review of the 2017 Final Rule

In the preamble of the 2017 final rule, EPA explained that it interpreted the requirements of TSCA section 6 to apply to conditions of use for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur, rather than to legacy uses, which EPA used as a term for continuing, *in-situ* uses of chemicals for which manufacturing, processing, or distribution in commerce had ceased (e.g., certain phased-out flame retardants present in textiles or furniture that continue to be used, asbestos-containing pipe wrap, etc.), or associated disposal. In addition, among other regulatory provisions, the 2017 final rule established that the submission of inaccurate, incomplete, or misleading information pursuant to a manufacturer-requested risk evaluation is a prohibited act subject to penalties under title 18 of the U.S. Code. The 2017 final rule also established requirements for information that must be submitted by a manufacturer when requesting that EPA conduct a risk evaluation (40 CFR 702.37(b)(4)) and that the submitted information be held to the scientific standards established in TSCA section 26(h) (40 CFR 702.37(b)(6)).

Several non-governmental organizations filed petitions for judicial review of the 2017 final rule, which were consolidated in the U.S. Court of Appeals for the Ninth Circuit (hereafter, the "Ninth Circuit") under *Safer Chemicals, Healthy Families v. USEPA*, on August 10, 2017 (Ref. 2). The Ninth Circuit issued its opinion on November 14, 2019, holding that the EPA unlawfully excluded "legacy uses and associated disposals" from the conditions of use that the agency would consider in any risk evaluation (Ref. 2). Also, at the Agency's request, the Ninth Circuit (1) vacated and remanded the rule provisions applying criminal penalties to the submission of inaccurate or incomplete information to

EPA pursuant to a manufacturer-requested risk evaluation, and (2) remanded without vacatur the rule provisions addressing the information requirements for, and application of the TSCA section 26 scientific standards to, a manufacturer-requested risk evaluation (Ref. 5).

The Court declined to rule on several other aspects of the challenge, including that the rule suggested EPA would make risk determinations on individual uses of a chemical instead of on the chemical itself, and statements in the preamble regarding broad discretion to choose to exclude conditions of use from the scope of the risk evaluations. The Court reasoned that petitioners' claim that EPA would make risk determinations on individual uses instead of on the chemical itself as the law required was not justiciable due to ambiguity in the 2017 final rule text. The Court noted it was unclear "whether the Agency will actually conduct risk evaluations in the manner [those litigants] fear[ed]" and that the claim was therefore not justiciable (Ref. 2). With regard to petitioners' claim that EPA intended to exclude conditions of use out of the scope of the risk evaluations, the court held that claim not ripe, but noted that it did "not interpret the language in the [2017 final rule] to say anything about exclusion of conditions of use" (Ref. 2).

### C. Review of the 2017 Final Rule Under Executive Order 13990

Executive Order 13990 instructs that the Federal Government be guided by the best science and be protected by processes that ensure the integrity of Federal decision-making, and established the Administration's policy of, among other concerns, following the science, improving public health and protecting the environment, limiting exposure to dangerous chemicals, reducing greenhouse gas emissions, and prioritizing environmental justice (EJ) when delivering on these concerns. Executive Order 13990 also instructs agencies to (1) review actions issued between January 20, 2017, and January 20, 2021, that may be inconsistent with or present obstacles to implementing the policy established in the order and, (2) consider suspending, revising, or rescinding such actions. Also on January 20, 2021, the Biden-Harris Administration issued a list of specific actions to be reviewed in accordance with Executive Order 13990 that included the 2017 final rule (Ref. 6).

EPA announced certain policy changes for TSCA risk evaluations on June 30, 2021 (Ref. 7) to ensure that risk evaluations follow the science and the law, including:

#### 1. Expanded Consideration of Exposure Pathways

Prior to June 30, 2021, the first 10 risk evaluations did not consistently assess air, water or disposal exposures to the general population based on an argument that these exposure pathways were already regulated, or could be regulated, under other statutes administered by EPA, such as the Clean Air Act, Safe Drinking Water Act, Clean Water Act, Resource Conservation and Recovery Act, or Comprehensive Environmental Response, Compensation, and Liability Act. The approach to exclude certain exposure pathways conflicted with the plain language of the law to evaluate chemical substances under the known, intended or reasonably foreseen circumstances associated with the full lifecycle of the chemical substance. It prevented consideration of relevant exposure information (e.g., information indicating presence of the chemical in air or water) in spite of statutory requirements that the Agency base its decisions on the best available science. The approach also resulted in a failure to consistently and comprehensively address potential exposures to the general population, as well as to certain potentially exposed or susceptible subpopulations. EPA announced it would no longer exclude consideration of such exposure pathways from TSCA risk evaluations.

#### 2. Assumptions About Use of Personal Protective Equipment (PPE)

Prior to June 30, 2021, EPA's TSCA risk evaluations generally assumed that workers were always provided and appropriately used PPE. However, as described in Unit III.G.1., data on violations of PPE use suggest that assumptions that PPE is always provided to workers, worn properly, and effective at eliminating exposures are not justified. In addition, TSCA requires that risk evaluations consider the known, intended or reasonably foreseen circumstances associated with the chemicals substance—including circumstances that result or could result in exposures to workers. For the reasons described further in Unit III.E.1., EPA believes that circumstances that result in occupational exposures to chemicals are reasonable to foresee, and, in many cases, known. As such, continued application of this general assumption could result in risk evaluations that underestimate risks, and in turn, prevent risk management rules from affording necessary protections. EPA announced that it would no longer assume that PPE is always used in occupational settings when making

unreasonable risk determinations for a chemical.

#### 3. "Whole Chemical" Risk Determination Approach

Prior to June 30, 2021, EPA made separate unreasonable risk determinations for each condition of use identified in the risk evaluation scope. EPA announced that, going forward, it would make the determination of unreasonable risk on "the chemical substance," rather than for each individual condition of use in isolation. As described further in Unit III.F.1., doing so going forward better aligns with the statute and Congress' intent, and enables the Agency's risk determinations to better reflect the potential for combined exposures across multiple conditions of use.

EPA invites public comment on the adoption of these changes in the amended procedural rule.

#### D. Agency Implementation

Since the 2017 final rule, EPA has finalized ten chemical risk evaluations under TSCA and published a draft supplement to the risk evaluation for 1,4-Dioxane. Additionally underway are 20 more risk evaluations on high-priority substances, a part 2 of the asbestos risk evaluation that will cover additional fiber types and "legacy" conditions of use, and several manufacturer-requested risk evaluations (Ref. 8). EPA is also developing a number of rulemakings to address unreasonable risks identified in these risk evaluations. The Agency has gained valuable experience in carrying out these actions and received a wealth of feedback on our procedures from public commenters and through scientific peer review. The proposed rule reflects lessons learned, efforts to increase efficiencies, and includes improvements to the process and requirements for manufacturer-requested risk evaluations that are more consistent with Agency scientific practices and policies. The proposed rule also includes some structural and substantive revisions for greater clarity and readability, and, more generally, to enhance the public's understanding of how EPA expects to carry out TSCA risk evaluations.

EPA intends that the provisions of this rulemaking be severable. In the event that any individual provision or part of this rulemaking is invalidated, EPA intends that this would not render the entire rulemaking invalid, and that any individual provisions that can continue to operate will be left in place.

### III. Proposed Amendments

#### A. Policy Objectives

The risk evaluation process established in 40 CFR part 702, subpart B outlines how EPA will determine, pursuant to TSCA section 6(b)(4)(A), whether a chemical substance presents an unreasonable risk of injury to health or the environment. EPA's general objectives for the proposed amendments, in keeping with the considerations addressed in Unit II, are to (1) better align the TSCA risk evaluation process with the statutory text and structure and Congressional intent, (2) ensure that the risk evaluation process under TSCA is consistent with the best available science and based on the weight of the scientific evidence, maintains the integrity of Federal decision-making, and upholds the policy in various Executive orders, (3) address the outcome of the Ninth Circuit litigation on the 2017 final rule, (4) apply lessons learned to date to improve the Agency's processes moving forward, and (5) enhance the public's understanding of how EPA expects to carry out subsequent TSCA risk evaluations. Through improvements to the risk evaluation process in these proposed amendments, EPA anticipates that any risk management actions following any determination that a chemical substance presents unreasonable risk will result in needed public health and environmental protections that limit exposure to dangerous chemicals, and, where applicable, address the climate crisis and advance environmental justice.

To accomplish these objectives, EPA is proposing targeted changes and clarifying edits to the existing process by which the Agency evaluates risk from chemical substances for purposes of TSCA section 6. Additionally, this proposal includes structural changes to the regulatory text to accomplish these goals. EPA is not proposing to establish highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this proposed rule seeks to ensure that the risk evaluation process is transparent, without unduly restricting the science that will be used to conduct the evaluations, allowing the Agency flexibility to adapt and keep pace with changing science as it conducts TSCA risk evaluations into the future.

#### B. General Provisions

##### 1. Applicability of Updated Procedures

EPA is proposing that the changes to the procedures as part of this rulemaking would be applied to all risk evaluations initiated on or after the date of the final rule. For risk evaluations in process as of the date of the final rule, EPA would expect to apply the proposed changes to those risk evaluations only to the extent practicable, taking into consideration the statutory requirements and deadlines. Where a change to a risk evaluation would prevent the Agency from meeting the statutory deadline, for example, EPA would generally not view that change as practicable. However, where applying a proposed change would impact timeliness but also ensure compliance with other statutory obligations (e.g., conducting an appropriately scoped risk evaluation), EPA would make a judgment on practicability by weighing the implications for public health and environment, defensibility from both a scientific and legal perspective, Agency priorities and the availability of resources. As a general matter, EPA believes that most of its ongoing risk evaluations, including the ongoing supplement to the 1,4-Dioxane risk evaluation and part two of the Asbestos risk evaluation, will likely conform to the changes contemplated in this NPRM, and does not anticipate significant challenges in this area. Finally, EPA does not expect to apply these procedures retroactively to risk evaluations already completed.

##### 2. Categories of Chemical Substances

EPA is proposing to clarify the regulations with respect to their applicability to risk evaluations on categories of chemical substances. Pursuant to TSCA section 26(c), wherever TSCA requires or authorizes EPA to take action on a chemical substance, EPA can take that same action with respect to a category of chemical substances (i.e., groups of chemical substances which are, for example, similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment). Although the rule's procedural requirements generally refer to "chemicals" or "chemical substances," EPA is proposing to clarify in the regulatory text at § 702.31(d) that those references also apply to categories of chemical substances.

#### C. Definitions

EPA is proposing changes to a number of definitions codified in the existing regulatory text. EPA is proposing to eliminate the codified definitions for "best available science" and "weight of scientific evidence." As described in greater detail in Unit III.I., EPA believes that defining these concepts in the rulemaking is both unnecessary and inhibits the Agency's flexibility to quickly adapt to and implement changing science. Not codifying regulatory definitions of these scientific terms is consistent with the approach in the 2017 proposed rule (Ref. 9) (hereinafter "2017 proposed rule") and was supported by public comment. Instead, as described in Unit III.I. EPA intends to ensure that its risk evaluations are consistent with Agency guidance and methodologies in applying these terms. As TSCA requires, at 15 U.S.C. 2625(h), EPA's risk evaluations will continue to use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science. Further, both risk evaluation and risk management decisions under TSCA section 6 will be based on the weight of the scientific evidence, as required by 15 U.S.C. 2625(i). EPA's expected application of these terms is more fully described in Unit III.G. regarding Risk Evaluation Considerations.

Second, and as described further in Unit III.G.4., EPA is proposing an addition to the examples identified in the definition of "potentially exposed or susceptible subpopulation" which currently include "infants, children, pregnant women, workers, or the elderly." The Agency proposes to add "overburdened communities" to better reflect the Agency's intent to consider risks to particular communities in the United States that potentially experience disproportionate environmental harms and risks, while also ensuring environmental justice—the fair treatment and meaningful involvement of all people regardless of race, color, culture, national origin, income, and educational levels with respect to the development, implementation, and enforcement of protective environmental laws, regulations, and policies—is considered where appropriate, including as part of any subsequent risk management action.

Finally, EPA is proposing minor updates to a number of other definitions to better align with existing Agency guidance. Specifically, the definitions for "pathways" and "routes" have been

adjusted for consistency with EPA's *Exposure Factors Handbook* (Ref. 10). Additionally, EPA is also proposing clarifying edits to the definitions for "aggregate exposure" and "sentinel exposure" to align with Agency guidance, and to make clear that the terms can apply not only to individual persons, but to the populations and environment when doing so is consistent with the best available science. EPA is not proposing to amend the definitions for "act," "conditions of use," "reasonably available information," "sentinel exposure," "uncertainty," or "variability."

#### D. Technical Corrections and Reorganization

The proposed rule reflects a number of minor updates and corrections and general organizational restructuring. For example, references to 15 U.S.C. 2605(b)(2)(A) have been removed in light of the fact that the law's one-time requirement related to identification of the first group of 10 chemicals for risk evaluation has been satisfied and is no longer applicable for purposes of the procedural rule. Additionally, EPA made minor updates to the regulatory text to correct typos and to ensure consistency in use of certain phrases (e.g., manufacturer-requested risk evaluations). More generally, EPA aimed to improve the readability of certain provisions, and, ultimately, enhance the public's ability to understand how EPA will undertake TSCA risk evaluations. As part of this effort, EPA is proposing to reorganize the sequence and structure of regulatory provisions to, for example, establish sections that distinguish between the components of the risk evaluation, the analytic considerations to be applied in the risk evaluation, and the associated procedural timeframes and actions. EPA welcomes comment on these changes to enhance clarity and readability. EPA has provided a short description of the reorganization:

- Proposed §§ 702.31, 702.33, and 702.35 have retained the same organization.
- Proposed § 702.37 "Evaluation requirements" includes many of the components of § 702.41 of the 2017 final rule, including statutory requirements of a risk evaluation, upholding the science requirements of section 26(h), inclusion of conditions of use, and clarity regarding making an unreasonable risk determination on the chemical substance. This section also includes EPA's approach to information and information sources, much of which is moved from § 702.41(b) in the 2017 final rule. New proposed language included

in this proposed section is EPA's approach to conducting a fit-for-purpose risk evaluation, addressing information gaps, and use of data gathering authorities.

- Proposed § 702.39 is a newly titled section "Components of risk evaluation" that is composed of 2017 final rule §§ 702.41, 702.43, 702.45. This one section includes the components of a risk evaluation (e.g., scope, hazard assessment, exposure assessment, risk characterization, risk determination) and what they must contain. Some of the specific requirements of the hazard and exposures assessment have been streamlined and reconfigured from the 2017 final rule.

- Proposed § 702.41 "Peer review" was § 702.47 in the 2017 final rule.

- Proposed § 702.43 contains the parts of a risk evaluation (e.g., draft scope, final scope, draft risk evaluation and final risk evaluation) and the process and timelines associated with the development and publication of these parts. Much of this section was moved from the 2017 final rule § 702.41. This proposed section now includes provisions pertaining to substantive revisions to these documents post publication.

- Proposed § 702.45 is the revised process for submitting a manufacturer requested risk evaluation, moved from the 2017 final rule 702.37.

- Proposed § 702.47 "Interagency collaboration" remains unchanged from 2017 final rule § 702.39. As part of EPA's commitment to identify information earlier in the prioritization and risk evaluation processes, the Agency expects to continue to engage and enhance coordination with other Federal agencies that may have chemical-specific information. Doing so will not only serve to inform the Agency's work in the risk evaluation, but can also help to proactively identify conditions of use that may be essential to national security, critical infrastructure, and/or mission critical uses, identify existing safety measures Federal agencies already have in place for their uses, and inform any subsequent risk management approaches.

- Proposed § 702.49 "Publicly available information" remains substantively unchanged from § 702.51 from the 2017 final rule.

#### E. Scope of TSCA Risk Evaluations

##### 1. Inclusion of All Conditions of Use

EPA is proposing a number of changes to the regulatory text to make clear that the scope of TSCA risk evaluations will not exclude any "conditions of use"

(i.e., any circumstance, based on reasonably available information, under which a chemical substance is known, intended or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of) to better align with the statutory text and structure, including modification to various provisions in the current rule that state or imply that EPA has broad discretion to choose which conditions of use it will or will not evaluate. These proposed amendments are intended to ensure that the scopes of future risk evaluations are determined in accordance with the law.

When TSCA was originally signed into law in 1976, there were tens of thousands of chemicals in commerce and the law imposed no mandate that EPA conduct any assessments to determine whether those existing chemicals present unreasonable risk of injury to health or the environment. While EPA did conduct some risk assessments on a handful of these existing chemicals prior to 2016, those assessments were focused on a specific subset of individual conditions of use of chemicals (e.g., paint and coating removal, vapor degreasing, etc.). The net effect of this use-by-use approach was that—even if EPA were to identify risks through a risk assessment and successfully promulgate a rule under TSCA to manage those particular risks—the public would still not have certainty regarding risks from the full spectrum of uses of the chemical substance. This uncertainty, in turn, would continue to erode public confidence in the safety of chemicals pervasive in our households, communities and the environment, and encourage states to adopt an increasingly complex patchwork of regulatory measures to address chemical risks.

One of the defining features of the 2016 amendments to TSCA was the mandate for EPA to systematically prioritize those thousands of existing chemicals for review, and then to evaluate their risks, holistically, under the chemical's "conditions of use"—a phrase that Congress defined to capture a chemical's full lifecycle, i.e., "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." (15 U.S.C. 2602(4)). While clearly a significant undertaking, Congress recognized that comprehensive progress on evaluating the universe of thousands of existing chemicals would not be made without this mandate, coupled with a strong risk-based safety standard and deadlines

for completing the work (Ref. 11). To allow EPA to continue to address only a subset of each chemical's uses as part of the new TSCA process would deny such comprehensive progress.

The question of whether the Agency has broad discretion under the law to exclude conditions of use from the scope of risk evaluations was the source of much discussion publicly during the development of the 2017 proposed and final rules. EPA believes the approach proposed herein is more consistent with congressional intent and reflects consensus of technical discussion with congressional negotiators leading up to the passage of the 2016 amendments. See also Ref. 11 at p. S3516 (implying the lack of discretion in the "mandate to consider conditions of use") and p. S3519 (referencing the prior TSCA risk assessments that did not consider "all conditions of use" and Congress' desire to nonetheless allow EPA to proceed with risk management based on those select "partial" risk evaluations). However, in the preamble to the 2017 final rule the Agency asserted that it retained discretion to exclude conditions of use from the scope of TSCA risk evaluations. Ref. 1 at p. 33729.

In support of this assertion of discretionary scoping authority in the 2017 final rule, EPA pointed to language in TSCA section 6(b)(4)(D) that requires EPA to identify the conditions of use in a scope document that the Agency "expects to consider" in a risk evaluation and the "as determined by the Administrator" phrasing in the statutory definition of "conditions of use" itself (Ref. 1 at p. 33729). EPA argued that such language gave the Agency discretion to select among the conditions of use and, ultimately, to exclude conditions of use from the scope of TSCA risk evaluations. EPA expressed at that time that those provisions empowered the Agency to exclude, for example, conditions of use that the Agency deemed "de minimis" in nature, or conditions of use where opportunities for exposure were likely to be limited (e.g., closed system or intermediate) (Ref. 1 at p. 33729). As discussed further in Unit III.E.3., EPA has also relied on this interpretation to exclude consideration of exposure pathways in TSCA risk evaluations where EPA or another regulatory agency had or could assess and regulate the same chemical—a policy that excluded exposures to the general population through air, water and disposal, and left potential risks unaccounted for.

Upon further review, and as described in the preamble to the 2017 proposed rule and supported by legislative

history, EPA believes that the better reading of TSCA's statutory text and structure is that EPA does not have discretionary scoping authority, and that risk evaluations are to be conducted on the circumstances under which the chemical is known, intended and reasonably foreseen to be manufactured, processed, distributed in commerce, used, and disposed of (*i.e.*, activities that constitute the "conditions of use" within the meaning of TSCA section 3(4)) (15 U.S.C. 2602(4)). The plain language of TSCA section 6(b)(4)(A) specifies that EPA must determine in a risk evaluation whether "a chemical substance" presents an unreasonable risk of injury to health or the environment "under the conditions of use." Similar language appears throughout section 6 of the law. See, for example, 15 U.S.C. 2605(b)(4)(G)(i) and (ii) stating that the risk evaluation "for a chemical substance" must be completed within 3 to 3.5 years of initiation. As such, while EPA at one time interpreted the statute to permit a different approach, the statute is better interpreted as requiring that the evaluation must be on the chemical substance—not a subset of individual conditions of use of the chemical substance. EPA also believes the purpose of the requirement to evaluate the "chemical substance" was to ensure that the Agency, through the risk evaluation process, would comprehensively determine whether a chemical substance, under the known, intended, and reasonably foreseen circumstances of manufacture, processing, distribution in commerce, use and disposal, presents an unreasonable risk. This reading also aligns with the requirements under the 2016 TSCA amendments to establish a constant pipeline of activity on assessing chemical substances and managing risks, effectively driving forward progress on the tens of thousands of unreviewed existing chemical substances in commerce (15 U.S.C. 2605(b)(2) and (b)(3)(C)). In the absence of comprehensive risk evaluations on chemical substances (*i.e.*, an approach that considered only a subset of a chemical's uses), the unevaluated uses would create uncertainty as to whether EPA had fully addressed a chemical's unreasonable risk and further delay progress on the backlog of existing chemicals.

Given these considerations, EPA believes that the phrase "as determined by the Administrator" in the statutory definition of "conditions of use" requires application of fact and professional judgment in determining

whether or not a particular circumstance is known, intended or reasonably foreseen—and should not be viewed as license to select among those circumstances in determining which should be included or excluded from the scope of a risk evaluation that is to be completed on a chemical substance (15 U.S.C. 2602(4)). Likewise, the instruction in TSCA section 6(b)(4)(D) for the Agency to—during the scoping phase—identify the conditions of use it "expects to consider" in a risk evaluation, is best read as directing the Agency to identify the uses and other activities that it has determined constitute the conditions of use of the chemical substance, while acknowledging that the Agency's expectations at the scoping phase may not always align perfectly with the conditions of use actually considered and assessed in draft and final risk evaluations. EPA may, for example, mistakenly identify a condition of use in the scope document, and later remove it from analysis in the risk evaluation. Alternatively, EPA might be unaware of or inadvertently exclude a condition of use during the scoping phase, but later incorporate it into its risk evaluation. While EPA at one time interpreted the language differently, EPA no longer believes that the "expects to consider" language in TSCA section 6(b)(4)(D) gives the Agency broad discretion to choose among conditions of use that it will include in a risk evaluation of a chemical substance. The Ninth Circuit agreed with this view, noting that the phrase "conditions of use that the EPA plans to consider" in the 2017 final rule and the similar phrase "expects to consider" in TSCA section 6(b)(4)(D) simply refer to the Agency's role in determining what the conditions of use are for a particular substance, and do not grant EPA discretion to exclude conditions of use from the scope of a risk evaluation (Ref. 2).

Consideration of all conditions of use in TSCA risk evaluations is also necessary from a scientific perspective to ensure development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment. Thus, consideration of all conditions of use ensures risk evaluations are consistent with the best available science and based on the weight of scientific evidence (15 U.S.C. 2625(h) and (i)). As discussed further in Unit III.G.2., there may be situations where certain conditions of use are associated with relatively lower exposures, but nonetheless in the aggregate those uses may contribute to

unreasonable risk. Exclusion of conditions of use from risk evaluations—irrespective of the Agency's intention in so doing—deprives the public of a complete picture of the chemical's risk, and may leave significant risk to human health or the environment unaccounted for and ultimately unaddressed.

For these reasons, the proposed rule clarifies that EPA will not exclude conditions of use (*i.e.*, any circumstances under which the chemical is known, intended or reasonably foreseen to be manufactured, processed, distributed in commerce, used or disposed of) from the scope of a risk evaluation by amending the regulatory text where it was either stated or implied that the Agency had broad discretion to exclude certain conditions of use from analysis.

## 2. Determination of “Conditions of Use”

Although EPA no longer interprets TSCA to allow the Agency to exclude any intended, known or reasonably foreseen conditions of use from the scope of a risk evaluation, EPA nonetheless retains authority to exercise judgment in making its determination as to whether a particular circumstance is intended, known, or reasonably foreseen, and therefore falls within the definition of “condition of use” for a particular chemical. As such, for each risk evaluation, EPA has and will continue to undergo a process to determine each chemical's conditions of use, analyzing reasonably available information and applying the facts, Agency expertise and professional judgment on a case-by-case basis. As described previously, the phrase “as determined by the Administrator” in the statutory definition of “conditions of use” requires EPA to review the reasonably available information and exercise judgment in determining whether a particular circumstance is intended, known or reasonably foreseen. For example, when information suggests that a circumstance of manufacture, processing, distribution in commerce, use or disposal is known to be occurring, EPA will determine that known circumstance to be a condition of use and include it within the scope of the risk evaluation, irrespective of other factors like the likelihood of that particular condition of use to be a significant contributor to risk. Likewise, where, in the Agency's professional judgment, a circumstance is reasonably foreseen to occur in the future, EPA will determine that circumstance to be a condition of use and include it within the scope of the risk evaluation, even where that condition of use may not

contribute significantly to the Agency's ultimate conclusions on risk.

In the preamble to the 2017 final rule (Ref. 1) EPA identified legacy disposal as falling outside the definition of “conditions of use.” EPA interpreted the TSCA definition for “conditions of use” as focusing on circumstances that are prospective or on-going, rather than reaching back to evaluate risks associated with legacy disposal (*i.e.*, disposal that has already occurred) (Ref. 1 at p. 33730). The Ninth Circuit agreed, holding that TSCA unambiguously does not require legacy disposals to be considered as conditions of use (Ref. 2 at pp. 425–426). The Court reasoned that a substance that has already been disposed of will not ordinarily be intended, known, or reasonably foreseen to be prospectively manufactured, processed, distributed in commerce, used, or disposed of again (Ref. 2). EPA is not reconsidering that issue in this proposal. However, EPA generally does not view any other categorical exclusions from the definition of condition of use as appropriate.

With respect to legacy use and associated disposal, however, EPA now believes that such circumstances are, in fact, “conditions of use” and must be considered in risk evaluations. (Ref. 2, pp. 420–421). An example would be in-situ asbestos insulation, a product no longer manufactured but nevertheless an ongoing downstream use. Future disposal of asbestos insulation is clearly an example of a chemical substance being “disposed of” and to the extent it is “intended” that such a substance be disposed of, or “known” that it will be, or if such disposal is “reasonably foreseen,” that circumstance unambiguously falls within TSCA's definition of “conditions of use.” (Ref. 2, pp. 420–421). As such, EPA is already developing a “part 2” of the TSCA risk evaluation for asbestos in order to include analysis of exposures and potential risks from legacy uses and expects future risk evaluations to also consider legacy uses and associated disposals as conditions of use (*i.e.*, circumstances associated with “use” and “disposal”). EPA believes that this approach is consistent with the statutory text and structure, as well as Congressional intent.

There are other categories of circumstances that EPA intends to consider in future risk evaluations associated with conditions of use that also bear mention. The known, intended, and reasonably foreseen production of a chemical as a byproduct or the known presence of a chemical as an impurity or within an article, for example, are squarely “conditions of

use” that generally must be included within the scope of risk evaluations.

Likewise, where EPA has reasonably available information demonstrating that certain exposures associated with a spill or leak are known or reasonably foreseen to occur during a condition of use that is part of a risk evaluation (*e.g.*, regular or predictable exposures from equipment leaks as part of the manufacturing process), EPA would expect to include that exposure within the scope of the risk evaluation. However, EPA would not expect to include within the scope of the risk evaluation exposures from releases of a chemical substance that are unsubstantiated, speculative or otherwise not likely to occur. For example, a future one-time accident involving the chemical substance that could be caused by an atypical one-time set of circumstances would generally not be assessed as part of a risk evaluation. Additionally, EPA would generally not include within the scope of the risk evaluation exposures associated with future extreme weather events (*e.g.*, hurricanes and wildfires). However, if information reasonably available to the Agency indicated that factors such as rising sea levels or extreme temperatures made worse by climate change were leading to regular and predictable changes in exposures associated with a given condition of use of a chemical substance, EPA would expect to consider those exposures within the scope of the risk evaluation. EPA requests comment on alternative proposals for considering potential climate-related risks. As discussed further in Units III.E.4. and III.I.2., EPA may adjust the level of refinement for a particular exposure assessment by conducting a “fit-for-purpose” assessment. While EPA will always apply the scientific standards required under TSCA, the depth or extent of analysis will be commensurate with the nature and significance of the decision. For example, EPA may find that the types of exposures described in this paragraph warrant consideration as part of an exposure assessment, either in a qualitative or a quantitative exposure assessment. Additionally, the Agency will decide the level of analysis warranted based on a number of factors, including but not limited to: the substance's physical-chemical properties; environmental fate and transport properties; the likely duration, intensity, frequency, and number of exposures under the condition of use; reasonably available information about the release; and other relevant considerations.

Even where a condition of use is not expected to be a significant contributor to risk from a particular chemical, TSCA nonetheless requires EPA to include it in the scope of the risk evaluation. However, and as described in Unit III.E.4., EPA has discretion to conduct its evaluations in a fit-for-purpose manner, which may justify tailoring the level of analyses to focus more detailed—and therefore more time and resource intensive—quantitative efforts on the conditions of use that pose the greatest potential for exposure and therefore risk.

### 3. Inclusion of All Exposure Pathways

In carrying out the first ten risk evaluations under TSCA, EPA narrowed the scope of those evaluations by excluding analysis of certain exposures to the general population from releases to air, water and land. The approach, which was not contemplated in the procedural framework rule but was first articulated in “Problem Formulation” documents published in 2018 (after the Final Scope documents) for each of the first ten chemicals undergoing risk evaluation, was premised on an argument that those pathways were already adequately assessed and managed—or could theoretically in the future be assessed and managed—under other EPA statutes and regulatory programs (Ref. 12). EPA further stated at that time that its intention was to use Agency resources efficiently under the TSCA program, avoid duplicating efforts taken pursuant to other Agency programs, maximize scientific and analytical efforts, and meet TSCA’s statutory deadline for completing risk evaluations. In the final risk evaluations for the first ten chemicals, EPA excluded exposure pathways that could be covered by regulatory programs under the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (e.g., drinking water pathways covered under the SDWA due to the existence of National Primary Drinking Water Regulations (NPDWRs) with chemical-specific, enforceable Maximum Contaminant Levels (MCL), or the inclusion of the chemical as an unregulated chemical on the Candidate Contaminant List (CCL)). EPA further asserted that this approach was supported by several TSCA authorities, including TSCA section 6(b)(4)(D), which gives the Agency authority to include the conditions of use that the Administrator “expects to consider” and section 9(b)(1), which allows

Administrator to use other EPA administered statutes, if the Administrator determines there is risk to health or the environment (Ref. 13).

This approach was criticized by the Science Advisory Committee on Chemicals (SACC), public commenters, and others (Ref. 14, 15, 16). As announced on June 30, 2021, EPA will no longer follow the approach and no longer intends to apply it to risk evaluations. Additionally, the Agency applied the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0* (Ref. 17) and additional feedback from peer review and public comment in order to consider whether its past failure to have assessed the risks associated with these exposures—along with its application of other past policies and interpretations—may have resulted in unaccounted potential risks. EPA has reconsidered the text of the relevant statutory provisions, overarching statutory structure and context, and legislative history, and no longer interprets the law to authorize exclusion of exposure pathways from the scope of TSCA risk evaluations because other EPA offices have already or could in the future regulate those chemicals. EPA’s prior interpretation in support of that approach was premised in large part on the Agency’s interpretation of TSCA section 6(b)(4)(D) as providing the discretionary authority to tailor the scope of exposures evaluated in TSCA risk evaluations. *See, e.g., Risk Evaluation for Methylene Chloride*, sec. 1.4.2 (Ref. 13). For the reasons explained in Unit III.B., EPA no longer interprets TSCA section 6(b)(4)(D) to provide broad discretionary authority to exclude conditions of use or exposure pathways from the scope of TSCA risk evaluations.

EPA also cited TSCA section 9(b)(1) as support for its approach, asserting that the instruction in that provision for the Administrator to “coordinate actions taken under [TSCA] with actions taken under other Federal laws administered [by EPA]” provided a broad, freestanding authority to exclude from the scope of TSCA risk evaluations exposure pathways that are addressed or could in the future be addressed by other EPA-administered statutes and regulatory programs. *See, e.g., Risk Evaluation for Methylene Chloride*, section 1.4.2 (Ref. 13). EPA asserted that such exclusions from TSCA risk evaluations were also permitted under the remaining text of TSCA section 9(b)(1), which establishes a process for determining whether to use EPA-administered authorities other than

TSCA to protect against a risk “[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws.” But upon reconsideration, neither provision in TSCA section 9(b)(1) is properly interpreted as authorizing exposure pathways to be excluded from TSCA risk evaluations.

Intra-agency coordination is integral to ensuring that EPA actions are well-informed, effective, and efficient, but a general requirement under TSCA section 9(b)(1) to “coordinate actions” cannot be read to displace the more specific requirements under TSCA section 6(b)(4)(F) to conduct a risk evaluation that shall “integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance,” and “take into account . . . the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance.” And the remaining text of TSCA section 9(b) is directed at risk management action, which cannot logically take place until after EPA has conducted an evaluation and determined that a risk is presented. If exposure pathways covered by other laws are not assessed in TSCA risk evaluations, it is unclear how the Administrator would have sufficient information to determine under TSCA section 9(b) that a risk to health or the environment associated with a chemical substance could be eliminated or reduced to a sufficient extent under another Federal law, or whether it is in the public interest to protect against such risk by actions taken under TSCA—a finding that must, pursuant to TSCA section 9(b)(2), consider “all relevant aspects of the risk.” Legislative history from TSCA’s original 1976 enactment supports this understanding that TSCA section 9(b)—the text of which was at that time split between TSCA section 9(b) and TSCA section 6(c) (pertaining to risk management rulemaking procedures)—is properly interpreted in the context of risk management action rather than any preceding evaluation of risk (Ref. 18). As explained in the Conference Committee’s 1976 report (Ref. 18) “the requirement to examine other EPA laws and to make determinations applies only when the Administrator takes regulatory action to protect against an unreasonable risk under this Act.”

EPA recognizes that there may be exposure-reducing impacts from existing regulations and intends to

consider reasonably available information when estimating exposures, including available monitoring data. There may also be circumstances where an unreasonable risk identified in the risk evaluation may be eliminated or reduced to a sufficient extent under the authorities contained in other Federal laws, such that a referral under TSCA section 9 might be appropriate. However, the mere existence of authority to assess or regulate a chemical, exposure pathway, or use under a statute other than TSCA does not equate to effective risk management of that chemical, exposure pathway or use, and an assumption that risk will—or could be—managed in the future cannot be used to satisfy the Agency's statutory obligations to evaluate existing chemical substances under TSCA and manage identified risks. Wholesale exclusion of identified exposure pathways for a chemical substance from the scope of the TSCA risk evaluation for that substance is inconsistent with EPA's obligations under TSCA section 6(b)(4)(F), as noted, as well as with requirements under TSCA section 26(h), (i) and (k) to make decisions based on science that are consistent with the best available science and are based on the weight of the scientific evidence, and to take into consideration reasonably available information relating to a chemical substance, "including . . . exposure information," under the conditions of use. Furthermore, TSCA section 9 already contemplates a time and place for determination of whether EPA or another Federal agency can adequately address chemical risks under the authority of another Federal law: during the risk management rulemaking process after the risk has been identified in a risk evaluation.

Accordingly, EPA is proposing changes in the rule to ensure that risk evaluations include all relevant exposure pathways, thereby providing the basis for development of strong, scientifically and legally defensible regulatory protections. Specifically, EPA is proposing to explicitly require that each risk evaluation assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other Federal statutes.

#### 4. Comprehensive But Fit-For-Purpose

While the changes described in Unit III.E.1. through 3. could all lead to future TSCA risk evaluations that are more comprehensive in scope, EPA recognizes the enormity of the challenge to complete these responsibilities within the timeframes set forth by

Congress. The law provides the Agency with only 3 to 3.5 years to finalize a TSCA risk evaluation. The primary purpose of a TSCA risk evaluation is to support regulatory decision making—either to form the basis of a subsequent rulemaking to eliminate identified unreasonable risk under TSCA section 6(a), or to determine that the chemical does not present unreasonable risk and therefore rulemaking is not necessary. Given the tens of thousands of existing chemicals, Congress further mandated that risk evaluations be completed on an ongoing basis and within specified timeframes.

Risk evaluations under TSCA should not be so complex or procedurally cumbersome that they cannot reliably be completed within the timeframes required by the statute. At the same time, EPA cannot produce partial or incomplete TSCA risk evaluations or otherwise pursue risk evaluations in a manner that is incompatible with the statutory framework. Although EPA must balance resource expenditure and manageability, it must do so within the confines of its statutory mandate. As such, EPA is proposing some changes to the rule to ensure consistency with TSCA's text, structure, and purpose, while also clarifying where the statute provides flexibilities in how EPA conducts TSCA risk evaluations. For example, the proposed rule makes clear that a risk evaluation must assess the full range of conditions of use and all exposure routes and pathways, and that a single risk determination will be made on the chemical substance, but these can be accomplished with a fit-for-purpose approach that allows for varying types and levels of analysis.

In order for TSCA implementation efforts to be sustainable, risk evaluations must be fit-for-purpose such that the Agency meets both the substantive statutory and regulatory requirements for conducting risk evaluations, while completing those evaluations within the statutory deadlines. (15 U.S.C. 2605(b)(4)). For example, while risk evaluations must consider the full spectrum of the chemical's conditions of use, not all of those conditions of use will warrant the same level of evaluation. As described in the 2017 final rule, EPA expects it may be able to complete its analysis on certain conditions of use and/or exposure pathways without extensive or quantitative evaluations of exposure. For example, lower-volume or less dispersive uses could receive less quantitative evaluations than uses with more extensive or complicated exposure patterns. In addition, not all identified toxicological endpoints may need the

same level of analysis and consideration. Efficiencies may be gained in similarly tailoring approaches to peer review and/or systematic review. EPA can make scientifically sound risk determinations, considering reasonably available information, consistent with the best available science, and based on the weight of scientific evidence, through a combination of different types of information and risk assessment approaches. Ultimately, the proposed changes—TSCA risk evaluations that are both more comprehensive (*e.g.*, that consider all exposure pathways) and better incorporate fit-for-purpose approaches that ensure EPA is meeting its statutory deadlines—will lead to more scientifically sound and legally defensible risk evaluations that support robust TSCA section 6(a) risk management rules that address any unreasonable risks of injury to human health or the environment.

#### 5. Additional Efficiencies

Based on the Agency's early implementation efforts and experience using the data gathering authorities afforded under the amended statute, it has become clear that EPA should identify, obtain, review, and synthesize data and information for risk evaluations much earlier in the TSCA existing chemical risk assessment and risk management process. Doing so will enable the Agency to finalize risk evaluations in the aggressive timeframes provided by the law, and as necessary, initiate risk management actions in a timely manner. EPA believes a more sustainable process would involve—either during prioritization or before—review of reasonably available information, identification of data needs and gaps, and preliminary efforts to scope the potential risk evaluation. Prioritization is the statutorily required initiating step in the TSCA existing chemical risk evaluation and risk management process. (15 U.S.C. 2605(b)). This 9- to 12-month process includes a risk-based screening to ultimately designate a chemical substance as a high-priority substance for risk evaluations or low-priority substance for which a risk evaluation is not warranted at the time. In the interest of creating additional efficiencies, EPA is proposing a process in which the Agency would publish and take comment during prioritization on preliminary information to inform the scope of the potential risk evaluation, which may result in the publication of the "draft scope" before the initiation of the subsequent risk evaluation.

More specifically, when early indications suggest the chemical is

likely to meet the criteria for a high-priority designation, EPA expects to publish the draft scope for public comment, to correspond with one of the two statutorily required 90-day comment periods associated with prioritization. Publishing this information early will allow the Agency to give an early indication as to the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Agency expects to consider and may provide early indications as to how the Agency expects to conduct a fit-for-purpose risk evaluation. This information will accompany the prioritization screening review criteria, and EPA will look to public comment and submission of available relevant data to inform both the final priority designation but also, if the chemical is then designated as a high priority, the information to inform the scope.

As the first statutorily required step of the risk evaluation process, TSCA requires the Agency to publish the scope of the risk evaluation no later than 6 months after initiating the risk evaluation. (15 U.S.C. 2605(b)(4)(D)). This scope must include the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider. Under the 2017 final rule, however, EPA must publish the scope in a “draft” form, followed by no less than a 45-day public comment period. The 2017 final rule states that the Agency generally expects to publish this draft no later than 3 months after initiation of the risk evaluation. Stakeholders supported this provision during the development of the 2017 proposed rule; due to the gravity of the “final” scope on the risk evaluation process and possible state preemption, it was important for stakeholders to have the ability to comment on the draft scope. The proposed rule would maintain the requirement to publish a draft scope but set forth an expectation to publish the information as early as the prioritization process (*e.g.*, concurrent with the proposed high-priority designation), to allow the Agency more time to review and effectively use the public input in the development of the risk evaluation’s scope. EPA requests comment on this proposed approach of publishing a draft scope during the prioritization process when it is clear that the chemical undergoing the prioritization process will be designated as a high-priority chemical.

#### F. Risk Determinations

##### 1. Determinations on the “Chemical Substance”

EPA is proposing to clarify the regulations with respect to the way EPA makes a risk determination at the conclusion of the TSCA risk evaluation process. As described earlier, EPA believes, as supported by the plain language in the law, that the chemical’s full spectrum of conditions of use must be included and assessed in the risk evaluation. EPA fully intends to continue to consider exposures associated with each condition of use. However, following that analysis, and for the reasons described in this Unit, the Agency no longer intends to make separate risk determinations for individual conditions of use. Instead, EPA is proposing changes to the regulations to clarify and codify the approach that the Agency originally proposed in the 2017 proposed rule (*i.e.*, to make a single risk determination on the whole chemical substance). EPA believes that this approach is consistent with the statutory text and structure, as well as Congressional intent, and will enable the Agency’s risk determinations to better reflect the potential for combined exposures across multiple conditions of use.

In the 2017 proposed rule, EPA proposed that risk determinations be made on the “chemical substance,” consistent with the plain language of the law and Agency’s interpretation of the new requirements in TSCA at that time. (Ref. 9 at pp. 7572, 7565 through 7566, and 7580). As described in the preamble, “TSCA section 6(b)(4)(A) specifies that a risk evaluation must determine whether ‘a chemical substance’ presents an unreasonable risk of injury to health or the environment ‘under the conditions of use.’ The evaluation is on the chemical substance—not individual conditions of use—and it must be based on ‘the conditions of use.’” Thus, in the 2017 proposed regulatory text, EPA proposed to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use. (Ref. 9 at p. 7480).

The 2017 proposed rule provided an exception that would allow EPA to make an “early determination” for a specific use that was deemed to present unreasonable risk. Where such an early determination was made, the risk management efforts to address that specific use could begin more expeditiously and not wait until the end of the 3 to 3.5 year risk evaluation process (Ref. 8 at pp. 7568 and 7578).

EPA did not propose a similar process for use-specific early determinations of no unreasonable risk. This exception made logical sense, in that, if a specific use of a chemical—in isolation—presented an unreasonable risk under TSCA, that chemical itself would necessarily present an unreasonable risk irrespective of risks posed by other uses. The converse may not be true. Where a specific use might not present an “unreasonable risk” on its own, it may nonetheless contribute to an unreasonable risk determination when considered together with other uses of the chemical (*e.g.*, when considering it in an aggregate exposure scenario).

EPA received comment on the 2017 proposed rule that limiting “early determinations” only to uses that present unreasonable risk was unfair, and encouraged the Agency to extend this concept of early, use-specific risk determinations to those uses determined not to present unreasonable risk. The 2017 final rule stated that “EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation, either in a single decision document or in multiple decision documents” (Ref. 1). There was one particular passage in the preamble to the 2017 final rule which stated that EPA would make individual risk determinations for all conditions of use identified in the scope. (Ref. 1 at p. 33744).

Concerns about a use-specific approach to risk determinations were raised as part of litigation on the final rule in *Safer Chemicals v. EPA* (Ref. 2 at p. 413), including that such an approach ignores the potential risks when the same individuals are exposed to the same chemical through multiple conditions of use (*e.g.*, in the workplace and in the home). Those exposures, when combined, may present unreasonable risk, whereas, when viewed in isolation, may not. A panel of the Ninth Circuit Court of Appeals recognized the ambiguity of the regulation on this point, and ultimately held that a challenge regarding “use-by-use risk evaluations [was] not justiciable because it is not clear, due to the ambiguous text of the Risk Evaluation Rule, whether the Agency will actually conduct risk evaluations in the manner Petitioners fear” (Ref. 2 at p. 413). Subsequent to the Ninth Circuit’s decision, EPA made individual risk determinations for each condition of use evaluated in the first ten risk evaluations (*i.e.*, the condition of use-specific approach to risk determinations). That approach was

based on the particular passage in the preamble to the 2017 final rule stating that EPA would make individual risk determinations for all conditions of use identified in the scope. (Ref. 1 at p. 33744). The approach resulted in a mix of findings that certain conditions of use for a chemical “present unreasonable risk” while others “do not present unreasonable risk.”

As announced in June 2021 as the path forward for the first ten risk evaluations, EPA has revisited this decision and determined to revise the use-specific risk determinations for most of the first ten chemicals to reflect a single determination on the chemical substance itself (Ref. 7). These revisions did not require the Agency to change any of its underlying analyses in the risk evaluations. In the case of many of these first 10 chemicals, EPA had already determined that many or most of the individual conditions of use presented an unreasonable risk.

In revising the risk determinations for the first 10 chemicals, EPA noted that in contrast to the portion of the preamble of the 2017 final rule that discusses the intent of the Agency to make multiple risk determinations, the regulatory text itself and other statements in the preamble reference a risk determination *for the chemical substance* under its conditions of use, rather than separate risk determinations for each of the conditions of use of a chemical substance. See for example, the revised risk determination for Methylene Chloride (Ref. 13). Notwithstanding the one preambular statement about condition of use-specific risk determinations, the preamble to the 2017 final rule also contains support for a risk determination on the chemical substance as a whole.

Although the Agency indicated in its June 2021 announcement that it would make a single risk determination on a chemical when it was “clear that majority of conditions of use warrant one determination,” EPA now believes a better understanding of the statute is that a single determination on the chemical substance is required in every instance, and is proposing to make this clear in this procedural rule. TSCA section 6(b)(4)(A) specifies that in a risk evaluation, EPA must determine whether “a chemical substance” presents an unreasonable risk of injury to health or the environment “under the conditions of use.” This language clarifies that the risk determination is on the chemical substance—not individual conditions of use—and it must be based on “the conditions of use.”

Although EPA previously found ambiguity in TSCA section 6(b)(4)(A), it now believes that a better reading of the statute in light of its content and structure (and other reasons described in this paragraph) is that it requires EPA to simultaneously evaluate all conditions of use of a chemical substance. TSCA section 6(a) requires EPA to apply risk-management requirements “to the extent necessary so that the chemical substance or mixture no longer presents such risk.” This phrasing suggests that the chemical substance presents the unreasonable risk, and not specific conditions of use. Further, TSCA section 6(i)(1) explains that “a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order.” Similarly, TSCA section 6(i)(2) explains that “a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be . . . a final agency action, effective beginning on the date of promulgation of the final rule.” Both of these provisions speak in terms of whether the chemical substance presents unreasonable risk. Neither provision mentions the conditions of use. The structure of TSCA section 6(i) also implies a binary decision by not addressing a scenario in which a chemical substance would be subject to TSCA section 6(i)(1) and (2).

EPA’s view that there should be one determination on the chemical substance is further bolstered by TSCA’s preemption provisions at Section 18, and its numerous references to “chemical substance.” In TSCA section 18(a)(1)(B)—titled “Chemical substances found not to present an unreasonable risk or restricted”—the law states that preemption applies, for example, when EPA issues “the determination” in TSCA section 6(i)(1) (*i.e.*, a determination that the chemical substance does not present an unreasonable risk). EPA notes in particular that the word “determination” in this provision is singular, suggesting Congress did not envision multiple determinations under TSCA section 6(i)(1). Additionally, TSCA section 18(a)(1)(B)(ii) states that permanent preemption is triggered by a final TSCA section 6(a) risk

management rule for “the chemical substance,” suggesting again that Congress did not envision that TSCA section 6(a) risk management rules would address only risks presented by individual uses or some subset of a chemical’s uses, but rather unreasonable risk presented by the chemical as a whole.

Based on its text and structure, EPA now reads TSCA as requiring the Agency, in each risk evaluation, to make a single risk determination of the chemical substance. EPA does not believe that the statutory text and structure permit the Agency to make separate risk determinations for each condition of use. The legislative history also tends to favor this reading, including Congressional floor statements made on the day of passage supporting the risk determination being for the chemical substance. “. . . EPA’s understanding of a chemical’s conditions of use . . . will be critical to EPA’s final determination of whether a chemical is safe or presents an unreasonable risk that must be controlled” and S3520 “A Section 6(i) order, determining that a chemical substance does not present an unreasonable risk under conditions of use, is similarly final Agency action applicable to all those conditions of use that were identified in the scope of EPA’s risk evaluation on the chemical substance.” (Ref. 11).

Although the Agency has previously referred to this as a “whole chemical” approach, this descriptor may have created some confusion regarding the Agency’s intent and purpose. EPA believes that a more accurate description of the approach is simply one where the Agency makes its risk determination for the chemical substance. A determination that a chemical substance presents an unreasonable risk does not mean that the entirety or whole of that chemical’s uses—or even a majority of uses—presents an unreasonable risk. Rather, EPA may determine that a chemical substance presents an unreasonable risk based on risk associated with even a single condition of use.

Some have criticized this approach in public comments on the revised risk determinations. They have noted, for example, that a singular risk determination could create confusion as to whether all uses or only certain uses of a chemical pose unreasonable risk. Fundamentally, EPA believes these concerns are risk communication issues that the Agency can and intends to continue to improve on. EPA will in every risk evaluation provide a rationale and explanation as to which conditions

of use or exposure pathways are significant contributors to risk. The Agency is committed to clearly communicating on the Agency's analysis of particular uses within the risk evaluation and will not make statements about the risk associated with the chemical substance absent such explanation. Rather, as indicated in the proposed regulatory text at 40 CFR 702.37(a)(5), and in order to inform risk management requirements, EPA generally expects every risk determination to identify which conditions of use are—or are not—significant contributors to EPA's determination that the risk presented is unreasonable. That said, for those chemical substances that EPA determines present unreasonable risk, the risk evaluation is not the end of the TSCA process. The primary purpose of a risk evaluation is not to provide the public with guidance or suggested actions with respect to particular chemical uses. Risk evaluations are scientific documents intended to inform EPA decisions as to whether regulatory action is needed to address unreasonable risks to human health or the environment. Ultimately, when the TSCA existing chemicals review process—including any TSCA section 6(a) rulemaking to manage risk—is complete, the public should have full confidence that the chemical can only be manufactured, processed, distributed in commerce, used and disposed of in accordance with the associated risk management requirements, and that the chemical substance no longer presents an unreasonable risk.

Likewise, others have expressed concern that EPA will use a singular risk determination to regulate in an overly broad manner. A determination of unreasonable risk for a chemical substance does not mean that EPA will, by default, propose or finalize a section 6(a) risk management rule requiring all manufacture or use of the chemical substance to be banned. EPA's statutory authority to regulate chemicals under TSCA section 6 is available only "to the extent necessary so that the chemical substance or mixture no longer presents [unreasonable] risk." (15 U.S.C. 2605(a)). EPA has a range of authorities available under TSCA section 6(a) to address unreasonable risk, including—but not limited to—requiring additional occupational safety measures, product labels, or concentration limits. Where such measures can eliminate unreasonable risk, EPA may propose them as part of the risk management rulemaking process. EPA's determination of appropriate regulatory

requirements will be on a case-by-case basis, and will not regulate chemical substances in a manner that is inconsistent with the requirements of TSCA sections 6(a) and (c)(2). For example, EPA may derive an exposure limit in the risk evaluation. Such a limit would necessarily be based solely on risk-related information, adhering to the statutory directive not to consider costs or other non-risk factors during the risk evaluation. However, because EPA is required to consider costs and other non-risk factors during the risk management phase, including whether uses of a substance are critical to Federal mission needs, or whether alternatives for a use of a substance exist, the exposure limit presented in a risk evaluation may not always or automatically signal the manner in which EPA will regulate occupational risks during the risk management phase.

It is important to note, however, in exercising EPA's authority under TSCA section 6(a) to ensure that "the chemical substance . . . no longer presents such risk," EPA may regulate conditions of use that do not themselves contribute to unreasonable risk for a given chemical. For example, where a risk evaluation's underlying analysis suggests that particular use downstream in the supply chain is significantly contributing to unreasonable risk determination for the chemical substance, EPA's risk management actions need not apply only to the downstream use. EPA may, for example, determine that elimination of the unreasonable risk requires regulation of the chemical's upstream manufacture, processing or distribution in commerce—even where the upstream activity itself does not directly result in the exposures that present the unreasonable risk.

EPA considered whether to propose a process for making use-specific early determinations of unreasonable risk prior to completing the risk evaluation for the remaining conditions of use, as contemplated in the original 2017 proposed rule. However, based on experience in conducting risk evaluations on the first 10 chemicals and implementing the new requirements in TSCA section 6, the notion of early, use-specific risk determinations is not practical or realistic within the statutory deadlines. The theoretical benefit of such an approach—enabling the early start of risk management efforts for the subset of uses that are clearly of highest risk—is outweighed by the burdens of managing the completion of multiple risk evaluation processes on a single chemical followed by potentially multiple rulemakings, each of which

must comply with statutory deadlines. In the event that there is a known, imminent and unreasonable risk of serious or widespread injury to health or the environment (*i.e.*, imminent hazard) associated with a use or chemical that the Agency needs to address immediately, TSCA section 7 provides EPA the authority to take such immediate action.

EPA believes the approach, consistent with the 2017 proposed rule, (*i.e.*, to make a single risk determination on the chemical substance) is aligned with the statutory text and structure, and will ensure that the Agency is best positioned to incorporate reasonably available information, make determinations consistent with the best available science and based on the weight of scientific evidence, including, where appropriate, risk determinations that consider aggregate exposure resulting from multiple conditions of use. (15 U.S.C. 2625(h), (i), and (k)). As such, EPA is proposing that risk evaluations will always culminate in a single risk determination on the "chemical substance" instead of individual risk determinations on individual conditions of use. EPA is proposing related conforming changes throughout the regulatory text, including the proposed addition of 702.37(a)(5) and the explicit mention of a single determination in 702.39(f)(1).

## 2. "Unreasonable Risk" Considerations

TSCA requires that a risk evaluation include a determination of whether or not a chemical presents unreasonable risk, and further requires that this determination be independent of cost or other non-risk factors. (15 U.S.C. 2506(b)(4)(A) and (F)(iii)). Neither TSCA nor the 2017 final rule define "unreasonable risk" given the inherently unique nature of each risk evaluation and the need for EPA to make this determination on a case-by-case basis. As described in the preamble to the 2017 final rule (Ref. 1 at p. 33735), EPA may weigh a variety of factors in determining unreasonable risk. The Administrator will consider relevant factors including, but not limited to: The effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible subpopulations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties.

The 2016 amendments also required that EPA's determination of unreasonable risk consider the risks to potentially exposed or susceptible subpopulations. Where EPA identifies risks as part of the risk evaluation, the risks to a potentially exposed or susceptible population may be more significant or severe than the risks to the general population. EPA would more explicitly reflect this statutory requirement in proposed § 702.39(f), as the 2017 final rule did not explicitly reference the statutory requirement to consider the risk to potentially exposed or susceptible subpopulations when making the final risk determination. Additionally, as discussed more fully in Unit III.G.4., the proposed rule clarifies that "overburdened communities" are one example of a group that may be considered as potentially exposed or susceptible subpopulations within a given risk evaluation. "Overburdened communities" may include various populations or communities in the United States that potentially experience disproportionate environmental harms and risks or multiple burdens from chemical exposure. The proposed change clarifies that EPA will consider the risk to potentially exposed or susceptible subpopulations as part of its determination of whether or not the chemical presents unreasonable risk.

Likewise, and as discussed further in Units III.G.2. and 3., EPA's determination of unreasonable risk from the chemical substance will also consider, where relevant, the Agency's analyses on aggregate exposures and cumulative risk. For example, where a single population is exposed to a chemical through multiple routes or pathways, EPA's assessment of those aggregate exposures may inform the determination of whether that chemical presents an unreasonable risk. Similarly, a cumulative risk assessment may be conducted on a category of chemicals, where the science supports this type of assessment, and the findings may inform the unreasonable risk determination for the category.

### G. Risk Evaluation Considerations

#### 1. Occupational Exposure Assumptions

EPA is proposing some clarifications to the assumptions that it will and will not apply in risk evaluations related to worker exposure.

In carrying out the first ten TSCA chemical risk evaluations, as part of the unreasonable risk determinations, EPA assumed that workers were provided and always used personal protective equipment (PPE) in a manner that

achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection. In support of this assumption, EPA relied on public comments indicating that some employers, particularly in the industrial setting, provide PPE to their employees and follow established worker protection standards (e.g., OSHA requirements for protection of workers). As EPA noted in prior risk evaluations (e.g., *Risk Evaluation for Methylene Chloride (Dichloromethane, DCM)*, 126 (Ref. 13 at p. 126), the consideration of assumed use of PPE in a risk determination could lead to an underestimation of the risk to workers. Further, parties in litigation as well as public commenters on several TSCA risk evaluations argued that making risk determinations based on assumptions of PPE conflates the risk evaluation and risk management phases. In June 2021, the Agency announced it would be revisiting the risk determinations that were based on these assumptions and noted its plans to consider information on use of PPE and other ways industry protects its workers during the risk management process (Ref. 7).

TSCA requires that EPA evaluate the chemical substance under the intended, known, or reasonably foreseen circumstances associated with the chemical's manufacture, processing, distribution in commerce, use and disposal. EPA believes that the blanket occupational exposure assumptions on PPE do not reflect the known or reasonably foreseen chemical exposures that impact workers, and their continued application in TSCA risk evaluations would result in underestimates of risk. For example, workers may be highly exposed because they are not covered by Occupational Safety and Health Administration (OSHA) standards, their employers are out of compliance with OSHA standards, or because the PPE is not sufficient to address the risk or their PPE does not fit or function properly. Further, many of OSHA's chemical-specific permissible exposure limits were largely adopted in the 1970s and have not been updated since they were established (Ref. 19). Additionally, TSCA risk evaluations are subject to statutory science standards, an explicit requirement to consider risks to potentially exposed or susceptible subpopulations, and a prohibition on considering costs and other non-risk factors when determining whether a chemical presents an unreasonable risk that warrants regulatory actions—all requirements that do not apply to

development of OSHA regulations. As such, EPA may find unreasonable risk for purposes of TSCA notwithstanding OSHA requirements. Where risk evaluations assume fully protective PPE use, and therefore little or no exposures for workers, the risk evaluations may underestimate and/or fail to identify unreasonable risk. EPA is requesting public comment on how the Agency can provide a transparent and detailed basis for the proposed unreasonable risk determination and existing chemical exposure limits derived from the risk evaluation process.

EPA is not suggesting that there is widespread non-compliance with applicable OSHA standards. In fact, EPA has received public comments from industry in response to various EPA documents associated with TSCA risk evaluations about occupational safety practices currently in use at their facilities, including adherence to OSHA standards and non-OSHA industry guidelines. EPA also acknowledges that other Federal agencies and their contractors that use chemicals may similarly have well-established occupational control measures in place. EPA will consider comments received during the risk evaluation process, as well as other information on use of PPE and other ways industry and Federal agencies protect their workers, as potential ways to address unreasonable risk during the risk management process. EPA recognizes that in some instances and in certain workplace locations, particularly advanced manufacturing facilities (e.g., those involved in the aerospace and defense industrial base industrial sectors) there could be well-established occupational safety protections in place. As EPA moves forward with risk management rules, the Agency will strive for consistency with existing OSHA requirements and/or best industry practices when those measures would address the identified unreasonable risk and would adopt a similar approach when making decisions about managing risks for uses of chemicals that are required to meet national security and critical infrastructure mission imperatives for other Federal agencies. EPA will proactively communicate with Federal agencies to identify such circumstances with an aim to propose measures in the risk management process to address occupational risk that will meet TSCA's statutory requirement to eliminate unreasonable risk of injury to health and the environment, while also leveraging ongoing interagency dialogue and striving to avoid potential

impacts to mission and infrastructure critical uses.

EPA is proposing regulatory amendments to clarify that, in future risk evaluations, EPA's consideration of occupational exposure scenarios in the exposure assessments will take into account reasonably available information, including information regarding known and reasonably foreseen circumstances where subpopulations of workers are exposed due to absence or ineffective use of personal protective equipment. The EPA intends to assess and include in the risk evaluation the use of PPE, any engineering controls, and other industrial hygiene practices at industrial, commercial, and Federal facilities. Where information is made available, the Agency will take into account known occupational control measures in the exposure assessments. However, the Agency will not consider, as part of the unreasonable risk determination, exposure reduction based on assumed use of PPE by workers. For purposes of the risk determination at § 702.39(f)(2), EPA would distinguish between an "assumed" use of PPE and a use that is supported by the reasonably available information and therefore known to be inherent in the performance of an activity. For example, where EPA has reasonably available information that substantiates use and effectiveness of PPE (e.g., information demonstrating that performance of a condition of use is impossible in the absence of PPE), EPA generally expects to take that information into account in the risk determination. The exposure reduction information (e.g., use of PPE) from the risk evaluation's exposure assessment would then be considered and incorporated in a future risk management action, as appropriate and as required pursuant to TSCA section 6(a), and we encourage commenters with interests or concerns on this to offer comments on this point in connection with such a future action.

## 2. Aggregate Exposure

Pursuant to TSCA section 6(b)(4)(F)(ii), when conducting a risk evaluation, EPA must "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration." While there is no mandate to conduct aggregate exposure analyses, EPA may conduct aggregate exposure analyses at its discretion. In the 2017 final rule EPA defined aggregate exposure as "the combined exposures to an individual from a single chemical substance across

multiple routes and across multiple pathways." In this proposed rule, EPA is proposing slight revisions to the definition. Aggregate exposure analysis is not only used to assess exposure to an individual, but may also be used to assess exposure for a population, subpopulation or the environment. Thus, EPA is proposing to strike "to an individual" from the definition, which is consistent with the definition used in *General Principles for Performing Aggregate Exposure and Risk Assessments* (Ref. 20). Additionally, EPA is proposing to strike "single" chemical, as TSCA allows the Agency to conduct risk evaluations on categories of chemicals.

The consideration of an aggregate exposure assessment may be particularly important for assessing chemical risks to overburdened communities. If a community is exposed to a chemical substance through multiple routes and/or pathways (e.g., exposure via air, land, and water or exposure via drinking water and water recreation) and/or from multiple sources (e.g., through different conditions of use occurring at multiple facilities), the Agency has the authority to aggregate those exposures, subject to the best available science standard, per TSCA section 26(h). Not only does the Agency have the authority, but in developing a comprehensive risk estimate for a chemical substance, it is the Agency's responsibility to consider the aggregation of what may be lower individual exposures from individual conditions of use and routes of exposure. EPA is committed to conducting an aggregate assessment, as supported by the science, in future TSCA risk evaluations. In an aggregate exposure assessment, it may be appropriate to also consider potential background exposures from non-TSCA uses that are not within the scope of the risk evaluation. EPA could also consider the disproportionate impacts that background exposures may have on overburdened communities to inform the final unreasonable risk determination.

## 3. Cumulative Risk

Advancing the science to support cumulative risk assessment is a high priority for the Agency. Cumulative risk assessment is applicable to all lifestages, and could inform the Agency's efforts to understand and mitigate those risks to potentially exposed or susceptible subpopulations, including children and overburdened communities. Several reports from the National Research Council (NRC)—including the 1994 report *Science and Judgment in Risk*

Assessment (Ref. 21) the 2008 report *Phthalates and Cumulative Risk Assessment: The Tasks Ahead* (Ref. 22), and the 2009 report *Science and Decisions: Advancing Risk Assessment* (Ref. 23)—have highlighted the importance of understanding the combined risk from multiple chemical stressors. These reports, as well as statutory requirements such as those presented in the Food Quality Protection Act of 1996 (Ref. 24), have helped drive EPA's evolving work on cumulative risk assessment. Because individuals are co-exposed to many chemicals in their daily lives, some of which may have the same health effects, EPA believes that in some cases the best approach to assess risk to human health may be to look at the combined risk to health from multiple chemicals.

Although TSCA does not mandate that EPA must conduct cumulative risk assessments, TSCA does require that EPA, when conducting TSCA risk evaluations in 3 to 3.5 years (15 U.S.C. 2605(b)(4)(G)), consider the reasonably available information, consistent with the best available science, and make decisions based on the weight of the scientific evidence (15 U.S.C. 2625(h), (i), and (k)). EPA recognizes that for some chemical substances undergoing risk evaluation, the best available science may indicate that the development of a cumulative risk assessment is appropriate to ensure that risk to human health and the environment is adequately characterized. TSCA also gives the Agency the authority to consider the combined risk from multiple chemical substances or a category of chemical substances. (15 U.S.C. 2625(c)). Under TSCA section 26(c), EPA may take "any action authorized" under any provision of TSCA, in accordance with that provision with respect to a category of chemical substances or mixtures of chemical substances. TSCA defines "category of chemical substances" as a group of chemical substances the members of which are similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment, or the members of which are in some other way suitable for the classification as such for purposes of [TSCA]." (15 U.S.C. 2625(c)). This definition provides EPA with the flexibility to group chemical substances for inclusion in a risk evaluation and a cumulative risk assessment when supported by the best available science.

There are multiple definitions of the term "cumulative risk assessment." For TSCA risk evaluations, the Agency is

currently relying on the definition in *EPA's Framework for Cumulative Risk Assessment* that defines cumulative risk assessment as “an analysis, characterization, and possible quantification of the combined risks to health and/or the environment from multiple agents and/or stressors” (Ref. 25). This could include evaluation of multiple chemical substances that jointly exert a common toxic effect. Exposures to these chemicals could occur through multiple exposure pathways and through multiple routes of exposure. EPA expects to use available EPA (Refs. 26, 27, 28, 29), OECD (Ref. 30), and World Health Organization/International Programme on Chemical Safety (WHO/IPCS) (Ref. 31) guidances that outline two principal considerations for grouping chemicals for inclusion in a cumulative risk assessment: (1) Toxicologic similarity; and (2) Evidence of co-exposure over a relevant timeframe.

A risk evaluation on a single chemical may not accurately provide a complete understanding of the risks to an exposed population, given simultaneous exposure to multiple chemicals. In turn, without considering the cumulative risk of chemicals, the Agency's risk mitigation may not fully be able to consider the public-health implications of various risk management options for reducing exposure. EPA is committed to considering applying cumulative risk assessment approaches, as appropriate and where such analysis, based on reasonably available information, represents the best available science, for future chemicals undergoing risk evaluation. The Agency developed and released a *Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act* (Ref. 32) and *Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substances Control Act* (Ref. 33) for public comment and peer review in February 2023. The Agency is considering feedback from both stakeholders and peer reviewers and EPA will continue to develop robust methodology for the inclusion of cumulative risk assessment in TSCA risk evaluations. EPA seeks comment on how the Agency could incorporate provisions for cumulative risk assessment into our risk evaluation procedures in a way that would accommodate future advancements in the science of cumulative risk assessment as well as ensure that the scope and complexity of any such assessments is consistent with that

envisioned by Congress when it established deadlines for conducting risk evaluations.

As described in Unit III.G.4., TSCA also explicitly requires EPA's risk evaluations to consider unreasonable risk to “potentially exposed or susceptible subpopulations,” and the statute provides authority to consider non-chemical as well as chemical stressors when identifying these subpopulations. Non-chemical stressors are factors found in the built, natural, and social environments including physical factors (*e.g.*, geographic location) and psychosocial factors (*e.g.*, poor nutrition) (Ref. 34). EPA's Office of Research and Development has defined cumulative impacts as the totality of exposures to combinations of chemical and non-chemical stressors and their effects on health, well-being, and quality of life outcomes (Ref. 34) and may or may not include toxicologically defined risk. EPA has not to date considered cumulative impacts in TSCA risk evaluations, but may in the future as appropriate data, methods, and guidance are available.

#### 4. Potentially Exposed or Susceptible Subpopulations

TSCA requires EPA to evaluate risk to “potentially exposed or susceptible subpopulation[s]” identified as relevant to the risk evaluation by the Administrator, under the conditions of use. (15 U.S.C. 2605(b)(4)(A)). TSCA defines the term as “a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly.” (15 U.S.C. 2602(12)). TSCA does not further define “greater susceptibility” or “greater exposure,” giving the Agency discretion to interpret these terms. Greater susceptibility could include increased risk of experiencing an adverse effect due to one's lifestage or a pre-existing condition or circumstance (*e.g.*, immune-compromised conditions, lifestyle factors such as smoking status or alcohol abuse, age, ethnicity, or sex). This is consistent with EPA's Policy on Children's Health to protect children from environmental exposures by consistently and explicitly considering early life exposures and lifelong health in all human health decisions. The Agency will use its discretion and interpret “greater exposure” to potentially include fence-line communities (*e.g.*, those communities in

close proximity to facilities emitting air pollutants or living near effluent releases to water) or body burden. Additionally, Congress' inclusion of “such as” allows EPA to potentially identify communities who “may be at greater risk than the general population.” Thus, EPA may evaluate any subpopulation that may be at greater risk due to greater susceptibility or exposure, and identify additional subpopulations other than those examples listed in the statute, where warranted.

To ensure that the TSCA risk evaluations conducted for existing chemicals fully consider and evaluate the risks to these vulnerable communities, EPA is proposing to amend the regulatory definition of “potentially exposed or susceptible subpopulations.” Specifically, EPA is proposing to add “overburdened communities”—communities that may be disproportionately exposed or impacted by environmental harms—to the list of example subpopulations. The disproportionality can be as a result of greater vulnerability to environmental hazards, lack of opportunity for public participation, or other factors. Increased vulnerability may be attributable to an accumulation of negative or lack of positive environmental, health, economic, or social conditions within these populations or places. The term describes situations where multiple factors, including both environmental and socio-economic stressors, may act cumulatively to impact health and the environment and contribute to persistent environmental health disparities. These situations may apply to communities with environmental justice concerns.

EPA's 2017 proposed rule proposed a definition of PESS that included more examples of PESS than set forth by Congress in the statutory definition. EPA did not finalize that definition as proposed. In response to public comments, the Agency explained that “it would be difficult for the Agency to list all the potential subpopulations that the Agency might have reason to include in a risk evaluation” and that EPA did not want to imply exclusion of other subpopulations. However, EPA now believes that it is appropriate to propose the addition of “overburdened communities” to the definition of PESS because it reflects the Agency's understanding and acknowledgment that exposure to a chemical substance may disproportionately impact communities already experiencing disproportionate and adverse human health or environmental burdens. Nothing in TSCA or this proposed rule

would prevent the Agency from identifying another group or subpopulation as a “potentially exposed or susceptible subpopulation” in a given TSCA risk evaluation and specifically considering those exposures and risks within.

To identify overburdened communities when conducting a risk evaluation, EPA will engage the public throughout the TSCA prioritization and risk evaluation processes, work with EPA offices such as the Office of Environmental Justice and External Civil Rights and the Office of Research and Development, and may use available screening tools, such as EJSCREEN (Ref. 35) or EnviroAtlas (Ref. 36). These and other tools may also allow the Agency to capture greater susceptibility or greater exposure using the data layers for socioeconomic factors (e.g., income/poverty, education) or location (e.g., housing, employment, geography), and for environmental indicators (e.g., air toxics cancer risk, respiratory hazard index, particulate matter levels, ozone, Superfund site proximity, hazardous waste proximity, proximity to multiple chemical manufacturing or processing facilities), which may provide information for future cumulative assessment. EPA also continues to develop approaches for assessing the risk to overburdened communities. For example, in 2022 EPA submitted for peer review the *Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities* (Ref 16). This proposed screening level methodology evaluated the potential chemical exposures and associated potential risks to fenceline communities, or communities in close proximity, and thus commonly at greater exposure, to chemical emission sources. The Agency continues to develop risk evaluation approaches to help determine risk from all relevant exposure pathways with an emphasis on exposures to these commonly overburdened communities.

#### H. Science Policy and Scientific Standards

##### 1. Scientific Guidelines and Procedures

Congress recognized the importance of Agency policies, procedures and guidance necessary to facilitate implementation of the 2016 amendments to TSCA. (15 U.S.C. 2625(l)(1)). This proposed rule, as does the 2017 final rule, codifies the use of appropriate Agency guidance in the development of risk evaluations (proposed § 702.37(a)(1)). Agency guidance and methodology documents, which may include publicly available

handbooks, frameworks, protocols, or any other process support documents have long provided process and method transparency to Agency scientific work products. The appropriateness of the documents relates to their application in the methods, approaches, and science policy decisions used in TSCA risk evaluations. For example, the *Exposure Factors Handbook: 2011 Edition* (Ref. 10), provides exposure assessors inside the Agency as well as outside, with data on standard factors to calculate human exposure to environmental agents. Other EPA guidance and methodology documents provide background for the development of the TSCA risk evaluations, specifically the *EPA Guidelines for Carcinogen Risk Assessment* (Ref. 37), and the *EPA Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens* (Ref. 38). EPA will continue to use these and other existing Agency guidances in the development of TSCA risk evaluations. EPA may develop and use additional guidance as needed using a transparent process.

##### 2. Peer Review

Science is the foundation that supports the work of EPA, and this is equally true for TSCA risk evaluations. The quality and integrity of the science are vital to the credibility of the Agency’s decisions and processes, including but not limited to the evaluation of risks from chemicals, determination of whether a chemical presents an unreasonable risk, decisions on how best to manage that risk, and ultimately the Agency’s effectiveness in pursuing its mission to protect human health and the environment. One important element in ensuring that decisions are consistent with the best available science and based on the weight of scientific evidence is to have an open, transparent and independent scientific peer review process along with opportunities for public comment.

EPA has a long-standing history of peer review and has shown its commitment to peer review in the TSCA program. TSCA section 26(o) required EPA to establish an advisory committee, known as the Science Advisory Committee on Chemicals (SACC), to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. EPA expects to continue to obtain scientific advice and peer review from the SACC. The 2017 final rule explicitly required peer review to be conducted on all risk evaluations, which the Agency did for each of the first ten risk evaluations (Ref. 8). Reports from those

peer review committees proved extremely instructive and resulted in more robust and scientifically defensible products and improvements to EPA methods used in the risk evaluation process.

The Agency remains committed to using peer review in the development of TSCA risk evaluations and any associated methods or approach type documents and proposes to retain the provision to require peer review in the risk evaluation process. However, EPA is proposing some modifications to the language from the 2017 final rule to provide increased clarity on both the guidance the Agency will use to conduct peer review and on what peer review will be conducted. First, the Agency proposes removing the reference to specific versions of guidance documents. The 2017 final rule names specifically the *EPA Peer Review Handbook 4th Edition 2015* (Ref. 39) and OMB’s *Information Quality Bulletin for Peer Review* (Ref. 40). While at the time of this proposed rule these documents were and still are applicable, the Agency recognizes that these documents may be updated and/or their names modified and seeks to avoid confusion as to which guidance documents will be used. The Agency proposes at § 702.41 to refer instead to “applicable peer review policies, procedures, guidance documents, and methods adopted by EPA and the Office of Management and Budget (OMB) to serve as the guidance for peer review activities. EPA interprets “applicable” to reference the most current versions and believes this change will appropriately incorporate any future versions of peer review guidance documents from both the Agency and OMB (i.e., the EPA Peer Review Handbook and OMB Final Information Quality Bulletin for Peer Review).

The peer review guidance documents discussed in this Unit III.H.2., as well as their predecessors, provide guidance on all aspects of the peer review process. This includes guidance on when to conduct peer review and on what should be considered in selecting the appropriate peer review approach, including allowable latitude for the type of peer review that EPA can conduct. In determining the appropriate type of peer review, EPA can consider the complexity of the information and any prior peer review of underlying information. EPA has previously used this flexibility in the TSCA program and sought a letter peer review, as opposed to, for instance, a committee established under the Federal Advisory Committee Act (FACA) (5 U.S.C. 10), to peer review new and updated information used in

the revised draft risk evaluation for Pigment Violet 29 (Ref. 41).

The Agency fully intends to uphold the EPA Peer Review Policy Statement, which states in part, “. . . For highly influential scientific assessments, external peer review is the expected procedure. For influential scientific information intended to support important decisions, or for work products that have special importance in their own right, external peer review is the approach of choice . . .” However, as discussed in the *EPA Peer Review Handbook 4th Edition*, there are circumstances when the additional peer review of influential products that have had adequate prior peer review may not be necessary (Ref. 39). As the Agency looks to the future of TSCA risk evaluations, it is expected that specific approaches may be used repeatedly, after due consideration of complexity, novelty, and prior peer review. That is, there may be situations when repeated peer review is not warranted.

For example, EPA did not peer review the *2020 1,4-Dioxane; Supplemental Analysis to the Draft TSCA Risk Evaluation* (Ref. 42). In response to peer review of the draft risk evaluation for 1,4-dioxane, published in September 2019 (Ref. 43), members of the SACC, as well as public commenters, highlighted omissions in the draft evaluation, specifically 1,4-dioxane exposures as a byproduct in products and general population exposure from the surface water pathway. As a result, those conditions of use from the presence of 1,4-dioxane as a byproduct in consumer use were included in the scope of a supplemental analysis to the draft risk evaluation. In that situation, because the analytical approaches to assessing the unreasonable risk associated with these conditions of use mirrored those approaches used for the conditions of use evaluated in the peer reviewed September 2019 draft risk evaluation and there was not new or novel scientific information to consider, the Agency determined that additional peer review was not warranted, but sought public comment on the supplemental analysis.

EPA believes that future risk evaluations and associated analyses may present similar circumstances for EPA’s consideration. Rather than peer reviewing an entire risk evaluation, in adhering to applicable guidance, it may be appropriate for EPA to conduct peer review on only portions or sections that constitute unreviewed influential information. EPA also expects that a TSCA risk evaluation may use peer reviewed products (e.g., risk assessments, hazard assessments,

models), or portions thereof, conducted by another EPA office or other authoritative body (e.g., state, national, or international programs), for which both the best available science and weight of scientific evidence standards were adhered to (see Unit III.I.1.). EPA’s Peer Review Handbook specifically references circumstances that may not necessitate additional peer review including “work that has been previously reviewed in a manner consistent with the OMB Peer Review [Bulletin] and EPA’s Peer Review Handbook” (Ref. 39). Thus, this portion or section of a TSCA assessment may not need additional peer review. To this end, EPA proposes to add clarity around what will be peer reviewed. The 2017 final rule stated that “the risk evaluation” will be peer reviewed. The proposed regulatory text at § 702.41 provides EPA’s expectation that peer review activities could be conducted on risk evaluations “or portions thereof.” EPA believes this provides the needed flexibility to conserve Agency resources and avoid redundant peer review. EPA requests comments on the proposed changes with respect to peer review, including whether the proposed addition of “or portions thereof” is consistent with OMB and Agency guidance.

Consistent with the 2017 proposed and final rules, EPA will not seek peer review of any determination as to whether the risk is “unreasonable,” which is an Agency policy determination. Consistent with OMB and EPA guidance, the purpose of peer review is the independent review of the science underlying the TSCA risk assessment not an evaluation of EPA’s policy determinations. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is “unreasonable.” (15 U.S.C. 2605(i)). This is consistent with the statutory purpose of the SACC, “to provide independent advice and expert consultation, at the request of the Administrator, with respect to the scientific and technical aspects of issues relating to the implementation of this title” (15 U.S.C. 2625(o)(2)).

#### *I. Scientific Standards*

TSCA section 6(h) and (i) require the Agency to make decisions under TSCA section 6 in a manner that is consistent with the best available science and based on the weight of scientific evidence. Specifically, TSCA section 26(h) requires that in carrying out TSCA sections 4, 5, and 6, to the extent the Agency makes decisions based on science, the Agency shall “use scientific information, technical procedures,

measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science.” The statute then lists considerations: (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information; (2) The extent to which the information is relevant for the Administrator’s use in making a decision about a chemical substance or mixture; (3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models. Section 26(i) states “the Administrator shall make decisions under sections 4, 5, and 6 based on the weight of scientific evidence.” TSCA does not define either “best available science” or “weight of scientific evidence” and there is no requirement in the statute to define them by rule. Codification of definitions has potentially broader impacts beyond TSCA section 6 risk evaluations and rules, including TSCA sections 4 and 5 actions, and potentially other applications outside of TSCA.

EPA received significant comment about the codification of definitions for these terms during the development of the 2017 proposed rule (Ref. 1 and Ref. 44). Some commenters noted that it is imperative that the Agency have specific criteria which would allow for consistency and transparency for how EPA will implement science. Others argued that since interested persons may submit risk assessments to the Agency for consideration (under TSCA section 26(l)(5)), it is necessary for the Agency to provide a standard and expectation. Many commenters noted that there are a number of ways the Agency could and has defined these terms across other statutory obligations and suggested this could be both a reason to codify TSCA-specific definitions, or to not codify them to avoid future limitations in implementation approaches. Others have argued that the risk evaluation rule should be reserved for process and procedure, and that codification of

specific process definitions would limit the Agency's ability to adapt to the changing science of risk evaluation, as well as the science that informs risk evaluation. Further, some argued that defining the terms would limit the flexibility afforded the Agency, and arguably the mandate, to implement and advance novel science.

EPA determined not to propose codifying definitions of either of these terms in the 2017 proposed rule (Ref. 9 at p. 7572), citing the need to remain flexible to changing science and approaches. The Agency argued at that time that further defining these terms was unnecessary and ultimately problematic. EPA noted that these terms have and will continue to evolve with changing scientific methods and innovation, and Agency guidance does and will provide the necessary description and processes to ensure consistency and transparency (Ref. 9 at p. 7572). Ultimately, EPA did codify definitions for both of these terms in the final rule, explaining that codification of these definitions would instill confidence, increase transparency, predictability, and provide the public with assurance that EPA will adhere to the requirements of the statute (Ref. 1 at p. 33731). EPA is proposing to eliminate the following definitions from the regulatory text for the reasons described in Units III.H.1. and 2.

#### 1. Best Available Science

In the 2017 final risk evaluation rule, the Agency defined best available science as science that is reliable and unbiased, and described the use of best available science as involving the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). The definition also identified other considerations as applicable, including the extent to which:

- The scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;
- The information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;
- The degree of clarity and completeness with which the data, assumptions, methods, quality

assurance, and analyses employed to generate the information are documented;

- The variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and
- There is independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

In general, EPA continues to believe this current definition of "best available science" is aligned with the Agency's views and the science requirements in TSCA section 26(h). The first part of this definition originated from the Safe Drinking Water Act (SDWA) (42 U.S.C. 300f *et seq.*) (Ref. 45), and second part of the definition is drawn verbatim from the considerations listed in TSCA section 26(h)(1) through (5). SDWA adopted a basic standard of quality for the use of science in agency decision making. Under 42 U.S.C. 300g–1(b)(3)(A), the Agency is directed, "to the degree that an Agency action is based on science," to use "(i) the best available, peer-reviewed science and supporting studies conducted in accordance with sound and objective scientific practices; and (ii) data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data)." The mandate to use the best available science with considerations enumerated in TSCA section 26(h) closely mirrors these requirements. Specifically, TSCA section 26(h)(5) refers to verified and peer reviewed science and scientific methods, and TSCA sections 26(h)(1) though (4) refer to the important considerations for the Agency when identifying and using data in a risk evaluation. This further comports with SDWA's quality standard for the dissemination of public information about risks of adverse health effects (42 U.S.C. 300g–1(b)(3)(B)).

The precedent-setting standards in SDWA are further discussed in the OMB Information Quality Guidelines. These guidelines "provide policy and procedural guidance to Federal agencies for ensuring and maximizing the quality, objectivity, utility, and integrity of information (including statistical information) disseminated by Federal agencies" (Pub. L. 106–554; 114 Stat. 2763A–153 through 2763A–154). The *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency* (Ref. 46, also referred to as EPA's Information Quality Guidelines) contain

EPA's policy and procedural guidance for ensuring and maximizing the quality of information disseminated in Agency work products. Section 6.4 of EPA's Information Quality Guidelines discuss how the Agency ensures and maximizes the quality of information used in risk assessment and specifically adopts the SDWA quality principles. EPA's Information Quality Guidelines go on to say: "In applying these principles, 'best available' usually refers to the availability at the time an assessment is made. However, EPA also recognizes that scientific knowledge about chemical risk is rapidly changing and that risk information may need to be updated over time." In general, EPA believes the SDWA definition of "best available science" and the associated guidelines and policies are all aligned with the science requirements enumerated in TSCA section 26(h).

However, EPA believes that codifying a definition of "best available science" in the Risk Evaluation procedural rule is unnecessary and potentially problematic as it could limit the Agency's ability, flexibility, and mandate to incorporate the best available science into TSCA risk evaluations. As such, EPA is proposing to eliminate the definition of "best available science" from § 702.33. EPA specifically requests public comment on the proposed elimination of the definitions, the need for such definitions, and the utility of definitions as the state of science evolves. As discussed previously, EPA believes the specifics of that definition are already reflected in the TSCA requirements and considerations for applying the best available science in section 26(h), and in the Agency's policies and procedural guidance. These considerations are also replicated in the proposed regulatory text at § 702.37(a)(2). The Agency does not believe codifying a definition of "best available science" provides any additional transparency or improves consistency.

Furthermore, while the use and consideration of "best available science" is discussed at length in both EPA and other Federal agency guidance documents, the definition is not codified in other Agency rulemakings. EPA believes that a specific definition should not be codified in this rulemaking. Under proposed § 702.37(a)(1), the Agency would use appropriate Agency guidance in the development of the TSCA risk evaluations. TSCA section 26(l) requires the Agency to use and develop guidance documents that are necessary in carrying out the statute. TSCA further requires the revisions of guidance

documents as necessary to “reflect new scientific developments and understandings.” Reliance on Agency guidance for determining the “best available science” in TSCA risk evaluations ensures the desired transparency and consistency, while still allowing for more nimble adaptation over time.

As the Agency identifies reasonably available information to inform a TSCA risk evaluation of a given chemical, EPA may consider existing risk assessments, or reviews performed on the chemical in question to be the best available science. This may include assessments conducted by EPA that adhere to existing Agency Guidance, use methodologies that have been externally peer reviewed, and undergo public comment. Similarly, the Agency may also look to consider assessments or portions of assessments conducted by other United States or international authoritative bodies. EPA may consider these existing assessments or reviews to represent the best available science as required under TSCA and use portions of them to directly inform a risk evaluation.

## 2. Systematic Review and Fit-for-Purpose Systematic Approaches

The 2017 final risk evaluation rule defined weight of scientific evidence (WOSE) as used in TSCA to include the use of a “systematic review method” with a “pre-established protocol” to “identify and evaluate each stream of evidence.” In turn, in implementation of this regulatory requirement, EPA has previously viewed this definition as requiring the Agency to conduct systematic review according to a protocol on each evidence stream. The first method used was the 2018 *Application of Systematic Review in TSCA Risk Evaluations* (Ref. 47). This method was reviewed by the National Academies of Science, Engineering, and Medicine (NASEM) and the study report published in 2021, *The Use of Systematic Review in EPA’s Toxic Substances Control Act Risk Evaluations* (Ref. 48), included several opportunities and recommendations to improve EPA’s systematic review process. In response to recommendations made by the NASEM, as well as comments received from the TSCA SACC and the public during the review of the first ten risk evaluations, EPA significantly updated the TSCA systematic review process and developed a systematic review protocol. The draft *TSCA Systematic Review Protocol* (Ref. 49) replaced the *Application of Systematic Review in TSCA Risk Evaluations*. As described in

Unit III.I.3., EPA is proposing changes to the WOSE definition to ensure that the concepts and principles of systematic review and WOSE are used in the evaluation of existing chemicals and are appropriately considered separately.

TSCA risk evaluations use reasonably available information to draw the conclusions that are supported by the best available science. Reasonably available information is identified and evaluated through unbiased, transparent and objective data collection and data evaluation, using systematic review methods. EPA believes that integrating appropriate and applicable systematic review methods and approaches into the TSCA risk evaluations are critical to meet the scientific standards as described in TSCA section 26(h). A systematic review approach to data collection and data evaluation provides more complete information than an informal or unstructured review and can reduce bias in data selection (Ref. 49). The principles of systematic review collection and evaluation of data and information have been well developed in the context of evidence-based medicine (e.g., evaluating efficacy in clinical trials) and more recently have been adapted for use across a more diverse array of scientific fields. A 2014 report by the National Research Council (NRC) describes systematic review as “a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies” (Ref. 50). There are also well-established principles of systematic review like “transparent and explicitly documented methods, consistent and critical evaluation of all relevant literature, application of a standardized approach for grading the strength of evidence, and clear and consistent summative language” (Ref. 50). Systematic review includes performing—as described and documented in a protocol—a methodical literature search, collection and screening, followed by data quality evaluation (addressing factors such as relevancy and bias), extraction, and integration, using a defined protocol, that can be applied across multiple lines of evidence. Any systemic approach EPA uses will follow this process.

The TSCA program will also continue to work with partners including EPA’s Office of Research and Development (ORD), the Office of Pesticide Programs, and the Office of Water (OW) to advance and implement tools, methods, and efficiencies to systematically collect and evaluate literature. The procedures required for ensuring objectivity, transparency and no bias in the

collection and review of data for TSCA risk evaluations must be flexible enough to account for the diversity of both hazard and exposure information necessary to inform TSCA risk evaluations, and implementable within the statutory deadlines. EPA will continue to develop and evolve its systematic approaches to data collection and evaluation for use in TSCA risk evaluations to meet these goals. EPA will continue to use the principles and tools outlined in the draft *TSCA Systematic Review Protocol* (Ref. 49), but the Agency will move to implement more chemical specific approaches that are more flexible and relevant for the types and quantity of information used in an individual risk evaluation. As such, systemic review approaches must be commensurate with the relevant complexity of the assessment and nature of the information available, and carried out in a manner that permits completion within the timeframes that Congress provided. EPA will look to streamline chemical-specific protocols and approaches while remaining consistent with systematic review principles. These systematic approaches will be transparent, fit-for-purpose, and specific to the needs of each chemical/category, while better aligning with the schedules for completion of the risk evaluation. The Agency is also exploring how to leverage consideration of systematic reviews and systematic review approaches from other EPA offices and authoritative bodies, or portions thereof, to achieve greater efficiencies in the process. Ultimately, application of systematic review and/or systematic approaches are necessary to help EPA identify useful evidence, inform judgments as to the “best available science” and “weight of scientific evidence” (WOSE), and can transparently support risk evaluations that are both scientifically robust and defensible.

## 3. Weight of Scientific Evidence

In the 2017 Final Rule, EPA defined the WOSE as “a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.” 40 CFR 702.33. The Agency believes this definition is problematic and inconsistent with typical risk assessment practice and is therefore proposing to eliminate the definition

from the regulatory text—instead relying on long-established Agency guidance documents to guide weight of scientific evidence analyses under TSCA.

The 2017 final rule conflates WOSE (also referred to as weight of evidence (WOE)) and systematic review. This conflation was identified and best described by NASEM's review of EPA's publication titled *Application of Systematic Review in TSCA Risk Evaluations* (Ref. 47). In their study report, *The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations* (Ref. 48), the NASEM reviewers state "this definition of WOE seems to say that the TSCA systematic review is itself a WOE evaluation. As such, the agency's legal obligation to conduct a WOE evaluation is fulfilled by the fact that systematic review is the basis for TSCA evaluations." The NASEM Committee goes further describing the confusion that results when the WOSE is used at one stage of the systematic review process to integrate the strength of the evidence judgment for each individual evidence stream into an overall conclusion for a health endpoint, whereas under the WOSE definition, the systematic review process itself is a weight of scientific evidence evaluation (Ref. 48). Throughout the report, the Committee notes the conflation of terms and goes on to suggest that changing the definition of WOSE within the risk evaluation procedural rule may alleviate the terminology confusion (Ref. 48).

In developing this proposed rule, the Agency reviewed several alternative definitions or descriptions of WOSE or WOE. It is clear there are certain principles of WOSE that are universal, including foundational considerations such as objectivity and transparency. The phrase WOSE or WOE is used by EPA and other scientific bodies to describe the strength of the scientific inferences that can be drawn from a given body of evidence, specifically referring to the quality of the studies evaluated, and how findings are assessed and integrated. EPA broadly uses the WOSE approach in many existing programs and has described the application of WOSE in Agency guidelines used to classify carcinogens. In the 2005 *Guidelines for Carcinogen Risk Assessment* (Ref. 37), EPA refers to the WOE approach as ". . . a collective evaluation of all pertinent information so that the full impact of biological plausibility and coherence is adequately considered." The Endocrine Disruptor Screening and Testing Advisory Committee (EDSTAC) referred to the WOE approach as ". . . a process by which trained professionals judge the

strengths and weaknesses of a collection of information to render an overall conclusion that may not be evident from consideration of the individual data" (Ref. 51). EPA believes WOSE inherently involves application of professional judgment, in which the significant issues, strengths, limitations of the data, uncertainties, and interpretations are presented and highlighted.

As noted by the National Academies of Science, "because scientific evidence used in WOE evaluations varies greatly among chemicals and other hazardous agents in type, quantity, and quality, it is not possible to describe the WOE evaluation in other than relatively general terms" (Ref. 23). EPA does not believe that even an alternative codified definition would add additional transparency or certainty to the required use of WOSE in TSCA risk evaluations. Additionally, the Agency believes that codifying a specific definition would inhibit the flexibility of the Agency to quickly adopt and implement changing science to ensure that each risk evaluation is fit-for-purpose to the chemical under review. As such, EPA is proposing to remove the current codified definition of weight of scientific evidence. The Agency welcomes comment on this approach.

EPA will instead rely on established Agency guidance documents to guide the required application of WOSE in TSCA risk evaluations. At this time, EPA will primarily look to four documents for implementing WOSE in TSCA risk evaluations: 2016 *Weight of Evidence in Ecological Assessment* (Ref. 52), *Guidelines for Carcinogen Risk Assessment* (Ref. 37), 2011 *Endocrine Disruptor Screening Program Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing* (Ref. 53), and 2022 *ORD Staff Handbook for Developing IRIS Assessments* (Ref. 54). These documents all similarly describe the WOSE assessment as based on the strengths, limitations, and interpretation of data available, information across multiples lines of evidence and how these different lines of evidence may or may not fit together in drawing conclusions. The results from the scientifically relevant published or publicly available peer-reviewed studies, gray literature, or any other studies or lines of evidence which are of sufficient quality and reliability, are evaluated across studies and endpoints into an overall assessment. WOSE assessments examine multiple lines of evidence considering a number of factors, including for example the nature of the effects within and across studies, including number,

type, and severity/magnitude of effects and strengths and limitations of the information. A summary WOSE narrative or characterization accompanies the detailed analysis and is intended to transparently describe the conclusion(s) and reasoning behind it/them. Specifically, the narrative or characterization generally explains the selection of the studies or effects used as the main lines of evidence and relevant basis for conclusions, and describes the overall strength of the evidence supporting a conclusion from the WOSE assessment.

#### *J. Process for EPA Revisions To Scope or Risk Evaluation Documents*

EPA is proposing some new procedures and criteria for whether and how EPA would endeavor to revise or supplement final scope documents, and draft or final risk evaluations. The 2017 final rule does not provide any such criteria or procedures. The proposed procedures provide greater certainty and transparency for stakeholders. Additionally, given the tens of thousands of existing chemical substances in commerce and EPA's responsibility to assess and manage risks from those chemicals through a statutory deadline-driven pipeline of prioritization, risk evaluation and risk management activities, EPA believes that some guardrails are necessary to ensure that the Agency continues to make forward progress on existing chemicals as Congress intended. Continuously revisiting final risk evaluations would drain the Agency's already limited resources and divert attention from other chemicals actively in the prioritization, risk evaluation or risk management phases. The criteria and procedures in this proposed rule would serve the law's purpose to move chemicals through the process within the statutory deadlines, and allow the Agency to move on to evaluating another high-priority substance, consistent with TSCA section 6(b)(3)(C).

Specifically, with respect to final scope documents, EPA is proposing that subsequent changes—if any—to the scope of the risk evaluation after publication of the final scope be reflected and described in the draft risk evaluation instead of a revised final scope document. EPA believes that, moving forward, any changes to the scope of the risk evaluation after publication of a final scope document are likely to be minimal based on the improved processes proposed in this NPRM, and EPA's expected rulemaking to implement a tiered data collection strategy to better inform data needs for prioritization and risk evaluation

candidates (Ref 57). However, in the event that changes to the risk evaluation scope during that period are more significant, EPA recognizes that public notice of those changes might be warranted. The proposal contemplates that EPA could, in its discretion, publish a notice in the **Federal Register** notifying the public that EPA has made information regarding changes to the risk evaluation scope available in the docket before releasing the draft risk evaluation.

Likewise, EPA is proposing to refrain from reissuing draft risk evaluations in a second draft form. Draft documents are, by their nature, subject to change. Rather than spending time and resources to develop and issue a revised draft risk evaluation, EPA instead expects to reflect and describe any changes to the draft document in the final risk evaluation. Where changes from draft to final are significant in nature, nothing in the proposed rule would prevent EPA from seeking additional advice or feedback from its independent scientific advisors or additional public comment on relevant topics, provided that such actions can be completed within the timeframes Congress contemplated for TSCA risk evaluations. This proposed clarification to the Agency's process ensures that feedback is appropriately considered and reflected without unduly delaying progress towards completion of the risk evaluation.

EPA is proposing a general practice for how and when to revisit final risk evaluations, and certain exceptions to that practice. As general practice, where circumstances warrant revisiting a chemical risk evaluation that has already been finalized—which EPA believes are likely to be infrequent—the Agency may identify that chemical as a potential candidate for high-priority designation, and follow the procedures at 40 CFR part 702, subpart A. EPA believes that this general practice aligns with Congress' intent for the Agency to work systematically through the universe of existing chemicals within the statutory framework and aggressive deadlines associated with prioritization, risk evaluation and risk management. (15 U.S.C. 2605(b)(2)(C) and (b)(4)(G)). Revisiting risk evaluations outside of re-prioritizing the chemical substance results in unanticipated and potentially unbudgeted work that can siphon resources from statutorily mandated responsibilities under TSCA section 6. Conversely, re-prioritizing the chemical provides the public with ample notice and opportunity to engage, provides anticipatable milestones and process,

and better positions the Agency to maintain a manageable workload.

Nevertheless, there may be certain circumstances where revisions to a final risk evaluation outside of re-prioritization of a chemical are in the interest of protecting human health and the environment. For example, as announced on June 30, 2021, EPA is revisiting the first 10 final risk evaluations to ensure they followed the science and EPA's renewed understanding of the law, and determined a path forward on a case-specific, chemical-by-chemical basis (Ref. 7). The outcome of those risk evaluations, which may have underestimated risks based on, among other things, policies of excluding certain conditions of use and entire exposure pathways from assessment, warranted this action. Although changes proposed in this NPRM should prevent the types of issues that justified reanalysis of the first ten chemical risk evaluations, the same principle—the need to revise a final risk evaluation to protect human health and the environment—might apply to, for example, a scientific error that meaningfully impacts the evaluation or the Agency's ability to appropriately address risks through rulemaking.

Where EPA endeavors to revise or supplement a final risk evaluation outside of re-prioritization, the proposed rule further requires EPA to follow the same process and requirements for TSCA risk evaluations described in this proposed rule, including publication of a new draft and final risk evaluation, solicitation of public comment, and, as appropriate, peer review.

#### *K. Process and Requirements for Manufacturer-Requested Risk Evaluations*

EPA is proposing a number of changes to the process and requirements for manufacturers to request a risk evaluation. TSCA section 6(b)(4)(C)(ii) allows a manufacturer or group of manufacturers to request that the Agency conduct a risk evaluation of a chemical substance (or category of substances) that they manufacture. TSCA section 6(b)(4)(C)(ii) directs EPA to establish the “form . . . manner and . . . criteria” for such requests by rule, which the Agency finalized in 2017. Based on experience in implementing that process to date, EPA is proposing some modifications to increase clarity and to better position the Agency to carry out manufacturer-requested risk evaluations (MRREs) moving forward.

The current process for MRREs, laid out in 40 CFR 702.37, has been

challenging for EPA in a number of ways. First, the 2017 final rule allows requests to contain information relevant only to conditions of use of the chemical that are of interest to the requesting manufacturer (40 CFR 702.37(b)(3)). Within a relatively short time after receiving a request, EPA must either grant or deny the request (40 CFR 702.37(e)(6)). By “granting” an MRRE request under the current regulations, EPA is acknowledging that it has all the information it needs to conduct the evaluation, creating some ambiguity as to whether additional information can be gathered during the process, including through use of EPA's TSCA section 4 or 8 authorities. The process effectively leaves the Agency with the heavy burden of identifying the remaining conditions of use, reviewing information that came in with the request, obtaining and reviewing additional available literature, and determining any missing information or data needs—all within a matter of months. The current process also provides that upon granting the request, EPA will initiate the risk evaluation, triggering the start of the three-year statutory deadline to complete the activity (40 CFR 702.37(e)(10)).

EPA has found that this process is unrealistic. In addition to needing more fulsome information included in incoming requests, and additional time to properly review requests and determine any additional information needs prior to initiating the evaluation, EPA also needs some flexibility in the process to pursue data collection or development during the risk evaluation. In general, EPA believes that the process and timeframes for reviewing incoming MRRE requests should be more akin to the process and timeframes that precede EPA-initiated risk evaluations. When considering whether a chemical is a good potential candidate for prioritization—including the chemical's readiness for evaluation from a data perspective—EPA has a significant amount of time to review and analyze available information, identify data gaps and needs, and pursue various data gathering strategies. On top of that, the prioritization process itself provides an additional 9 to 12 months and two 90-day public comment periods to help the Agency refine its approach and deepen its understanding of the chemical—all before initiating the risk evaluation and the associated deadlines.

The proposed rule is intended to address these challenges. Units III.K.1. through 4. Describe the key proposed changes to the process for MRREs, and EPA's expectations for implementation moving forward:

### 1. Submission of MRRE

The law allows for submission of a MRRE by one or more manufacturers of a chemical substance, and both the current and proposed rule maintain that requirement as part of the regulatory text. However, in cases where multiple manufacturers jointly submit a MRRE (*i.e.*, a consortium), EPA expects to treat a consortium as a single entity for purposes of any regulatory determinations with regard to the requests, fee payments, and other general communication regarding the MRRE request and/or the risk evaluation. Joint submitters must designate a single point of contact for Agency engagement, and are otherwise collectively responsible for providing complete and sufficient information to the Agency to support the risk evaluation.

### 2. Scope of Request

Currently, the rule allows manufacturers to request a risk evaluation on particular conditions of use of interest, leaving the Agency with the heavy burden of identifying the remaining conditions of use. EPA is proposing that manufacturers only be permitted to make requests for evaluations of entire chemical substances—not individual conditions of use or subsets of conditions of use. In addition to better aligning with the statutory language in TSCA section 6(b)(4)(C) (stating that EPA “shall conduct and publish risk evaluations . . . on a chemical substance . . .”) and the scope of EPA-initiated risk evaluations, EPA believes this clarification will also encourage more robust, well-crafted submissions and better position the Agency for success in carrying out the evaluations. EPA recognizes that a requesting manufacturer may not have access to all necessary information to support the risk evaluation, and, as described in Unit III.K.4, EPA is also proposing a process to address these shortcomings. However, the proposed clarification regarding scope—along with changes described in Unit III.K.3.—would ensure no misgivings about the scope of MRREs and the information needed to support those requests in order for the Agency to undertake a risk evaluation.

### 3. Contents of Request

EPA is also proposing some key changes to the supporting information that must be included in a MRRE request. As a general matter, EPA believes that the requesting manufacturer(s) should bear the primary burden of providing EPA with all

information necessary to conduct a risk evaluation on the chemical substance. Congress also shared this sentiment in section 2 of TSCA, stating that “adequate information should be developed with respect to the effect of chemical substances and mixtures on health and the environment and that the development of such information should be the responsibility of those who manufacture and those who process such chemical substances and mixtures.” 15 U.S.C. 2601(b). Within respect to MRRE requests, Congress authorized EPA to establish the “form . . . manner and . . . criteria” for such requests in order to support successful implementation. (15 U.S.C. 2605(b)(4)(C)). The 2017 final rule’s allowance for the requesting manufacturer(s) to only provide supporting information relevant to their preferred conditions of use inappropriately shifts much of the information gathering burden to the Agency. Instead, EPA believes, as discussed in Unit III.K.2., based on TSCA’s statutory text and structure, that MRRE requests should attempt to identify all intended, known and reasonably foreseen circumstances of the chemical’s manufacture, processing, distribution in commerce, use and disposal, and provide all available information regarding the chemical’s hazards and exposures—not just information of relevance to the submitter’s interests. As such, EPA is proposing changes that would require more fulsome information as part of the request, based on information that is known to or reasonably ascertainable by the requesting manufacturer.

More specifically, EPA is proposing to require that manufacturers include a listing of the chemical’s conditions of use (*i.e.*, the circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of), and all information known to or reasonably ascertainable by the requesting manufacturer that supports the identification of those circumstances. While EPA must ultimately determine the chemical’s conditions of use for purposes of the risk evaluation, this requirement ensures a reasonable level of due diligence on the part of the requesting manufacturer to gather available information and provide it to EPA. Similarly, EPA is also proposing that incoming requests include “all information known to or reasonably ascertainable by the requesting manufacturer on the health and environmental hazard(s) of the chemical

substance, human and environmental exposure(s), and exposed population(s).” The proposed rule also provides some clarifications as to the specific types of information that must be included as part of the request. Under the 2017 final rule, requesting manufacturers are required to provide this information only where relevant to the particular uses of interest, leaving EPA with significant work not just to identify the remaining conditions of use, but also to locate and review available literature and quickly determine whether there is sufficient information to carry out a risk evaluation. The proposed changes put more of this responsibility on the requesting manufacturer. EPA believes that requesting manufacturers should be making a reasonable amount of effort to gather all available information on the chemical—whether that information is available to the general public, or otherwise available to the manufacturer—and compile it for the Agency’s review as part of an MRRE.

Information that is known to or reasonably ascertainable by the manufacturer would include all information in a person’s possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. The standard requires an exercise of due diligence, and the specific information-gathering activities that may be necessary for manufacturers to achieve this standard may vary from case-to-case. In the context of preparing a MRRE request and to meet the requirements in the proposed rule at § 702.45(c), EPA believes that due diligence would, at a minimum, involve a thorough search and collection of publicly available information on the chemical’s hazards, exposures and conditions of use. EPA would further expect that requesting manufacturers conduct a reasonable inquiry not only within the full scope of their organization regarding manufacturing processes and products (including imports), but also outside of their organization to fill gaps in knowledge. For example, such activities might include inquiries to upstream suppliers or downstream users or employees or other agents of the manufacturer, including persons involved in the research and development, import or production, or marketing for information pertinent to the criteria listed in the proposed rule.

EPA nonetheless still anticipates that manufacturers may not be in a position to provide the Agency with all the information necessary to complete the risk evaluation. EPA received comments

on the original 2017 proposed rule, for example, that manufacturers who do not produce the chemical for a particular use may not be able to obtain information pertaining to that use. To address this issue, EPA is proposing a process described further in Unit III.K.4. to formalize how such shortcomings will be identified and addressed. In short, where the requesting manufacturer is unable to provide all the information EPA needs for risk evaluation, the requesting manufacturer can request EPA use its information collection authorities under TSCA sections 4 (require manufacturers (including importers) or processors to test chemicals and report their findings), 8 (require reporting on chemical manufacturing, processing, and use, or require the submission of unpublished chemical health and safety information from manufactures (including importers), processors, or distributors), or 11 (ability to inspect facilities where chemicals are manufactured, processed, stored, or held before or after their distribution in commerce), to fill in the gaps. Where the information need is identified after the risk evaluation has already been initiated, the requesting manufacturer must also suspend its request to allow sufficient time for the Agency to exercise those authorities. These changes set clearer expectations for what EPA needs to undertake in a risk evaluation, and establish a process for productive engagement with requesting manufacturers toward meeting those needs.

#### 4. EPA Process for Reviewing Requests

EPA is proposing a number of changes to how the Agency will review MRREs. As described in this Unit, the current process simply does not allow enough time for thoughtful review of requests and consideration of potential information needs. As such, at § 702.45(e) of the regulatory text, EPA is proposing changes to the steps the Agency will take upon receipt of a MRRE, including additional measures for transparency and public engagement. The following is a general description of the proposed procedural steps:

**Notice of Receipt.** EPA will provide the public with notice within 15 days that a MRRE has been received. Although the proposed rule does not specify the means of notice, EPA expects to generally do so through updates to its website and email listserv notifications.

**Initial Review for Completeness.** EPA will then begin reviewing the request and supporting information against the requirements in the proposed rule to

determine whether or not the request appears complete. Requests that are clearly missing key required information in § 702.45(c) or are otherwise not well-supported will be rejected and returned to the submitter as incomplete. For example, EPA would consider a request for evaluation of category of chemicals incomplete where the request does not provide a rationale as to why the categorization is appropriate under TSCA section 26(c). Likewise, where a request fails to describe the circumstances related to the full lifecycle of the chemical substance (*i.e.*, manufacture, processing, distribution in commerce, use and disposal) or to provide an explanation as to why such information is unavailable to the requestor, EPA may reject the request as incomplete. During this step, EPA may also make an initial judgment as to the quality or quantity of information provided by the requesting manufacturer(s) and the sufficiency of that information to support a risk evaluation. Where the information is generally of poor quality, or when very little information is provided, EPA may also reject the request.

This initial review step allows the Agency to screen incoming requests before advancing to the more time- and resource-intensive steps associated with reviewing a MRRE. Where EPA determines a request to be incomplete, the requesting manufacturer can simply supplement and resubmit the request. Where EPA initially determines the request to be complete, EPA will advance to the next step in the process: public notice and opportunity for comment.

**Public Notice and Comment.** Where EPA initially determines the request to be complete, EPA will submit a notice of receipt of the MRRE for publication in the **Federal Register** within 90 days. EPA will also open a docket that includes all non-CBI and CBI-sanitized information included in the request and provide no less than a 60-day public comment period. EPA may also solicit specific comments on the request, including feedback on the conditions of use listed by the manufacturer in the request and information regarding sufficiency of available information to support a risk evaluation.

**Secondary Review for Sufficiency.** From the start of the public comment period, EPA would expect to begin conducting a more in-depth review of the request to determine whether there is sufficient information to support a reasoned evaluation on the chemical substance. Concurrently, EPA expects to conduct an internal cursory review of other reasonably available information,

however more comprehensive information collection would occur post-granting of the request. For EPA-initiated risk evaluations, EPA has clearly indicated that it would not expect to initiate the prioritization process until there is sufficient information to complete both the prioritization and risk evaluation processes. Likewise, EPA would not expect to grant an MRRE until confident that there is a similar level of information to support evaluation. As described in the proposed rule, EPA may determine that certain information gaps can be addressed through application of assumptions, uncertainty factors, models, and/or screening, consistent with TSCA section 26, without the need for additional data. EPA's review during this period would encompass both the information provided with the request and any additional relevant information that may be uniquely available to EPA (*e.g.*, TSCA CBI data that may not otherwise be known to or reasonably ascertainable by the requesting manufacturer). Following the close of the public comment period, EPA will further consider feedback from the public as to the sufficiency of available information. For example, if public comments indicate there are additional conditions of use, and the request does not identify or provide information relevant to those conditions of use, EPA may deem the request insufficient and return to the submitter for further consideration and possible supplementation.

EPA may also determine during this period whether there are deficiencies in the request, including data quality considerations, not identified during EPA's initial review for completeness. EPA's review for sufficiency will be completed within 90 days from the end of the public comment period. For requests determined not to be supported by sufficient information during this period, EPA will reject the request—effectively ending the Agency's review—and notify the requesting manufacturer. EPA generally expects to keep the public apprised of the status of requests through updates to its website. The requesting manufacturer would have the opportunity to further supplement and resubmit their request to EPA. Additionally, where the submitter believes that the information is not reasonably ascertainable by them, they can include in their resubmission a request—as described in this Unit—that EPA exercise its information gathering authorities to collect and/or develop information necessary to remedy the deficiency. For requests

determined to be supported by sufficient information, EPA will proceed with granting the request and continuing the review process.

*Grant.* As described elsewhere in this Unit III.K.4., and subject to the percentage limitations in TSCA section 6(b)(4)(E)(i)(II), EPA will grant MRRE requests that are both complete and supported by sufficient information. Under the 2017 final rule, a “grant” of a MRRE request effectively means that EPA has determined it has all information needed to conduct such risk evaluation. While EPA intends to make every effort to ensure sufficient information before granting a MRRE request, absolute certainty is not possible. Given the nature of risk assessment and public processes associated with TSCA risk evaluations, there may be occasion where EPA becomes aware of critical information needs later in the process. As such, the proposed rule specifically reserves the right for EPA to identify additional information needs for the risk evaluation at any time, including after granting the MRRE request.

*Publication of Draft Conditions of Use and Request for Information.* EPA will next publish a notice in the **Federal Register** that sets out, in draft form, the Agency’s preliminary determination on the chemical’s conditions of use, taking into account information provided in the MRRE request, information received during the first public comment period, and EPA’s own further review efforts. This notice will request relevant information from the public, and provide no less than a 60-day public comment period. Given that a chemical’s conditions of use are such an important component to define the scope of the risk evaluation, EPA felt it was important to share its understanding and provide an opportunity for additional feedback before formally initiating the MRRE. In the context of EPA-initiated risk evaluations, EPA expects this engagement to occur during the prioritization process, and, similarly, before the formal initiation of the risk evaluation and start of the statutory deadline for completion. Within 90 days following the close of the public comment period in this paragraph, and depending on the nature of comments received, EPA will either initiate the risk evaluation or notify the requesting manufacturer of any additional information needs.

*Initiation of Risk Evaluation.* Upon initiation of the MRRE, EPA will follow all requirements in this proposed rule including but not limited to proposed sections 702.37 through 702.49. EPA

will notify the manufacturer that the MRRE has been initiated, and similarly expects to keep the public apprised of the status through updates to its website. As indicated previously, EPA is reserving the right to identify additional information needs at any time during the risk evaluation process, including post-initiation.

*Identification of Information Needs.* Where additional information needs are identified at any time before the MRRE has been granted, the proposed rule provides a clear process for supplementation and resubmittal of the request. However, where additional information needs are identified at any point following EPA’s grant of the MRRE, EPA will notify the requesting manufacturer(s) and set a reasonable amount of time, as determined by EPA, for manufacturers to respond to the Agency’s notice. In response to EPA’s notice, the manufacturer can choose to (1) provide the necessary information to EPA, (2) if the risk evaluation has not yet been initiated, withdraw the MRRE request, or (3) request that EPA obtain the information using authorities under TSCA sections 4, 8 or 11.

Where a manufacturer chooses to provide—or develop and provide—the necessary information, EPA will set a reasonable amount of time for the requesting manufacturer to provide that information to EPA. Upon receipt of the new information, EPA will review the information within 90 days and determine whether or not it satisfies the identified need—again providing notice to the requesting manufacturer of its determination, and keeping the public apprised of the status of the MRRE on its website. EPA would further endeavor, to the extent possible, to make the supplemental information publicly available in the docket.

Alternatively, in the event the risk evaluation has not yet been initiated, the requesting manufacturer may withdraw the MRRE request. This option gives the requesting manufacturer some flexibility in the event that developing the necessary information would be considered too costly or time consuming. Any fees to be collected or refunded would be determined in accordance with this proposed rule and the TSCA fee provisions in 40 CFR 700.45. MRRE requests cannot be withdrawn by the requesting manufacturer once EPA has initiated the risk evaluation.

Lastly, where the requesting manufacturer believes that they can neither collect nor develop the identified information, they may request that EPA obtain the information using its authorities under TSCA sections 4, 8

or 11. As part of such a request, the manufacturer must provide a rationale as to why the information is not reasonably ascertainable to them. EPA will review the request and provide notice of its determination to the requesting manufacturer as to whether or not use of these authorities is warranted. Where EPA agrees to use its authorities, EPA will review the new information within 90 days of receipt and determine whether or not it satisfies the identified need—again providing notice to the requesting manufacturer and keeping the public apprised of the status of the MRRE on its website. EPA would further endeavor, to the extent possible, to make the supplemental information publicly available in the docket.

EPA recognizes that Congress clearly intended for those requesting MRREs to cover either 50% or 100% of the costs to carry out the risk evaluation. See 15 U.S.C. 2625(b)(4)(D). However, in the event that EPA exercises its authorities to gather additional necessary information, costs may be imposed upon entities other than the requesting manufacturer. For example, if EPA issues a test order under TSCA section 4 to support a MRRE, another entity could have to pay both the test order fee as well as the costs of developing the information. While the costs to EPA would be reflected in the final invoice to the requesting manufacturer, EPA is seeking comment on, to the extent that test orders are issued to support a MRRE, whether EPA should amend the regulation to allow the entire test order fee to be directed to the requesting manufacturer, even where an order is issued to another entity who is not the requesting manufacturer.

*Unfulfilled Information Needs.* EPA believes it is important that the procedures in this proposed rule account for a scenario in which information needs are not met, and the Agency is simply unable to complete the risk evaluation. In circumstances where EPA has identified additional data needs, but the requesting manufacturer(s) is unable or unwilling to fulfill those needs in a timely manner, has produced information that is insufficient to meet the need as determined by EPA, or where EPA determines that a request to use gather information under TSCA sections 4, 8 or 11 is not warranted (e.g., where the information is ascertainable by the manufacturer or the request does not provide a sufficient rationale), the proposed rule at § 702.45(g) contemplates that EPA can deem the MRRE request to be constructively withdrawn (i.e., EPA would construe

the MRRE request to be withdrawn even in the absence of a request to withdraw). Any fees to be collected or refunded would be determined in accordance with this proposed rule and the TSCA fee provisions in 40 CFR 700.45.

Fees for MRRE will generally be determined in accordance with 40 CFR 700.45. However, this proposed rule further specifies that in the event that a MRRE request is withdrawn after it has been granted—either by the requesting manufacturer or constructively withdrawn by EPA—the total fee amount due will be either, in accordance with 40 CFR 700.45(c)(2)(x) or (xi) (as applicable), 50% or 100% (respectively) of the actual costs expended in carrying out the risk evaluation as of the date of receipt of the withdrawal notice. The payment amount will be determined by EPA, and invoice or refund issued to the requesting manufacturer as appropriate.

#### IV. Requests for Comment

EPA requests comment on all aspects of the proposed rule discussed in this Unit III., including comment on whether the proposed rule would enhance transparency and public understanding of EPA's TSCA risk evaluation process and better align with the 2016 amendments to TSCA under the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114–182, 130 Stat. 448). Additionally, within this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. For ease of review, this section summarizes those specific requests for comment.

1. EPA requests comment on how the Agency could consider potential climate-related risks in a risk evaluation.

2. EPA requests comment on the proposed approach of publishing a draft scoped during the prioritization process when it is clear that the chemical undergoing the prioritization process will be designated as a high-priority chemical.

3. EPA requests public comment on the proposed elimination of the definitions of best available science and weight of scientific evidence, the need for such definitions, and the utility of definitions as the state of science evolves.

4. EPA requests comments on the proposed changes to the process of a manufacturer requested risk evaluation. In regards to cost, while the costs to EPA would be reflected in the final invoice to the requesting manufacturer, EPA is seeking comment on, to the extent that test orders are issued to

support a MRRE, whether the entire test order fee should also be directed to the requesting manufacturer, even where the order is also issued to another entity. Additionally, EPA requests specific comment on the burden estimate of a manufacturer requested risk evaluation, including the assumptions used in estimating the burden (*e.g.*, number of requests EPA expects).

5. EPA requests comment on general approaches or best practices for improving engagement with small entities. Early engagement with and feedback from all those who manufacture, process, distribute, use or dispose of a chemical is critical for the Agency to be able to accurately identify and characterize that chemical's conditions of use for consideration in the risk evaluation, EPA is seeking comment on how to improve its outreach to the stakeholder community, including education on the TSCA risk evaluation process for small entities.

6. EPA requests public comment on how the Agency can provide a transparent and detailed basis for the proposed unreasonable risk determination and existing chemical exposure limits derived from the risk evaluation process.

#### V. Reliance Interests

The proposed rule includes some statutory interpretations that differ from those previously held by the Agency at the time it issued the 2017 final rule, and, as part of developing this proposed rule, EPA has considered to what extent stakeholders may have reliance interests in those previous interpretations. EPA believes that there are either no reliance interests on those past statutory interpretations, or that any such interests are minor. The current rule and proposed changes largely pertain to internal Agency procedures that guide the Agency's risk evaluation activities under TSCA and mostly do not directly impact external parties, with one exception being modified procedural requirements for voluntary requests for risk evaluation submitted by manufacturers. However, to the extent there were any reliance interests on the prior interpretations, or the risk evaluations that were developed based on the previous procedural requirements, nothing in the proposed rule is intended to apply retroactively. EPA does not believe stakeholders have reliance interests pertaining to the process for future, yet-to-be-completed risk evaluations that will be carried out in accordance with this proposed rule.

#### VI. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not itself physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act; Final Rule. **Federal Register** (82 FR 33726, July 20, 2017) (FRL–9964–38). <https://www.govinfo.gov/content/pkg/FR-2017-07-20/pdf/2017-14337.pdf>.
2. U.S. Court of Appeals for the Ninth Circuit. *Safer Chemicals, Healthy Families v. USEPA*, No. 17–72260 No. 17–72501 No. 17–72968 No. 17–73290 No. 17–73383 No. 17–73390, Opinion. November 14, 2019. 943 F.3d 397, 425–426. <https://cdn.ca9.uscourts.gov/datastore/opinions/2019/11/14/17-72260.pdf>.
3. Executive Order 13990. Protecting Public Health and the Environment and Restoring Science to Tackle the Climate Crisis. **Federal Register** (86 FR 7037, January 25, 2021). <https://www.govinfo.gov/content/pkg/FR-2021-01-25/pdf/2021-01765.pdf>.
4. U.S. EPA. Information Collection Request (ICR) for the Proposed Rule: Procedures for Chemical Risk Evaluation Under TSCA. EPA ICR No.: 2781.01 and OMB Control No. 2070–NEW.
5. *Safer Chemicals, Healthy Families; et al., v. U.S. Environmental Protection Agency*, No. 17–72260, 17–72501, 17–72968, 17–73290, 17–73383, 17–73390, 2019 WL 6041996 (9th Cir. Nov. 14, 2019).
6. The White House, Briefing Room. Fact Sheet: List of Agency Actions for Review. January 20, 2021. <https://www.whitehouse.gov/briefing-room/statements-releases/2021/01/20/fact-sheet-list-of-agency-actions-for-review/>.
7. U.S. EPA. EPA Announces Path Forward for TSCA Chemical Risk Evaluations. Press Release. June 30, 2021. <https://www.epa.gov/newsreleases/epa-announces-path-forward-tsca-chemical-risk-evaluations>.
8. U.S. EPA. Assessing and Managing Chemicals under TSCA. Chemicals Undergoing Risk Evaluation under TSCA. <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/chemicals-undergoing-risk-evaluation-under-tsca> (Accessed May 31, 2023.)
9. U.S. EPA. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances; Proposed Rule. **Federal Register**. (82 FR 7562, January 19, 2017) (FRL–9957–75). <https://www.govinfo.gov/content/pkg/FR-2017-01-19/pdf/2017-01224.pdf>.

10. U.S. EPA. Exposure Factors Handbook: 2011 Edition. EPA/600/R-090/052F. Office of Research and Development, National Center for Environmental Assessment. Washington, DC. 2011. <https://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=236252>.
11. U.S. Senate Congressional Record, 162 Cong. Rec. S3511-01 (daily ed. June 7, 2016). <https://www.congress.gov/114/crec/2016/06/07/CREC-2016-06-07-pt1-PgS3511.pdf>.
12. U.S. EPA. Problem Formulation of the Risk Evaluation for 1,4-Dioxane. EPA/740/R1/7012. Office of Chemical Safety and Pollution Prevention. Washington, DC. 2018. <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0723-0064>.
13. U.S. EPA. Risk Evaluation for Methylene Chloride (Dichloromethane, DCM) CASRN: 75-09-2. EPA-740-R1-8010. Office of Chemical Safety and Pollution Prevention. Washington, DC. 2020. <https://www.regulations.gov/document/EPA-HQ-OPPT-2016-0742>.
14. TSCA Science Advisory Committee on Chemicals. Peer Review for EPA Draft Risk Evaluation for Methylene Chloride. Meeting Minutes and Final Report No. 2020-1. March 2020. <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0437-0080>.
15. Comment from the Attorneys General of Massachusetts, California, Hawaii, Maine, Maryland, New Jersey, New York, Oregon, Vermont, Washington, and the District of Columbia. Comments submitted to EPA in response to Notice of Availability on Problem Formulations for the Risk Evaluations to be Conducted Under the Toxic Substances Control Act and General Guiding Principles to Apply Systematic Review in TSCA Risk Evaluations. <https://www.regulations.gov/comment/EPA-HQ-OPPT-2016-0723-0074>.
16. Safer Chemicals, Healthy Families et al. Comments submitted to EPA on Notice of Availability on Risk Evaluation Problem Formulations Documents for Ten Chemical Substances under the Toxic Substances Control Act. <https://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0723-0089>.
17. U.S. EPA. Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0. EPA/744/D/22/001. Washington, DC. 2022. [https://www.epa.gov/system/files/documents/2022-01/draft-fenceline-report\\_sacc.pdf](https://www.epa.gov/system/files/documents/2022-01/draft-fenceline-report_sacc.pdf).
18. Conference Committee Report on TSCA, Public Law 94-469, Senate Rep. No 94-1302 at 85 (1976) Conf Rep. <https://www.congress.gov/bill/94th-congress/senate-bill/3149>.
19. OSHA. Permissible Exposure Limits Annotated Tables. <https://www.osha.gov/annotated-pels>. (Accessed May 30, 2023).
20. U.S. EPA. General Principles for Performing Aggregate Exposure and Risk Assessment. Office of Pesticide Programs. November 28, 2001. <https://www.epa.gov/sites/default/files/2015-07/documents/aggregate.pdf>.
21. NRC. Science and Judgment in Risk Assessment. The National Academies Press. Washington, DC. 1994. <https://dx.doi.org/10.17226/2125>.
22. NRC. Phthalates and Cumulative Risk Assessment: The Task Ahead. National Academies Press. Washington, DC. 2008. <https://dx.doi.org/10.17226/12528>.
23. NRC. Science and Decisions: Advancing Risk Assessment. National Academies Press. Washington, DC. 2009. <https://dx.doi.org/10.17226/12209>.
24. Food Quality Protection Act. 5.U.S.C. 136 et. seq.
25. U.S. EPA. Framework for Cumulative Risk Assessment. EPA/630/P-02/001F. Risk Assessment Forum. Washington, DC. May 2003. [https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk\\_cum\\_risk\\_assmnt.pdf](https://www.epa.gov/sites/default/files/2014-11/documents/frmwrk_cum_risk_assmnt.pdf).
26. U.S. EPA. Guidelines for the Health Risk Assessment of Chemical Mixtures. **Federal Register**. (51 FR 34028, September 24, 1986) (FRL-2984-3). <https://www.govinfo.gov/content/pkg/FR-1986-09-24/pdf/FR-1986-09-24.pdf#page=158>.
27. U.S. EPA. Supplementary Guidance for Conducting Health Risk Assessment of Chemical Mixtures. EPA/630/R-00/002. Risk Assessment Forum. Washington, DC. August 2000. <https://cfpub.epa.gov/ncea/cfm/recordisplay.cfm?deid=20533>.
28. U.S. EPA. Guidance on Cumulative Risk Assessment of Pesticide Chemicals That Have a Common Mechanism of Toxicity. Office of Pesticide Programs. Washington, DC. January 14, 2002. <https://www.regulations.gov/document/EPA-HQ-OPP-2007-0797-0001>.
29. U.S. EPA. Pesticide Cumulative Risk Assessment: Framework for Screening Analysis Purpose. Office of Chemical Safety and Pollution Prevention, Office of Pesticide Programs. Washington, DC. April 12, 2016. <https://www.regulations.gov/document/EPA-HQ-OPP-2015-0422-0019>.
30. OECD. Considerations for assessing the risks of combined exposure to multiple chemicals (No. 558 296). In Series on Testing and Assessment No 296. Paris, France. 2018. <https://dx.doi.org/10.1787/ceca15a9-en>.
31. Meek, M.E.; Boobis, Alan R.; Crofton, Kevin M.; Heinemeyer, Gerhard; Van Raaij, Marcel; Vickers, Carolyn. Risk Assessment of Combined Exposure to Multiple Chemicals: A WHO/IPCS Framework. *Regulatory Toxicology and Pharmacology*. July 1, 2011. 60:S1-S14. <https://dx.doi.org/10.1016/j.yrtph.2011.03.010>.
32. U.S. EPA. Draft Proposed Principles of Cumulative Risk Assessment Under the Toxic Substances Control Act. EPA/740/P/23/001. Office of Chemical Safety and Pollution Prevention. Washington, DC. February 2023. <https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0008>.
33. U.S. EPA. Draft Proposed Approach for Cumulative Risk Assessment of High-Priority Phthalates and a Manufacturer Requested Phthalate Under the Toxic Substances Control Act Control Act. EPA/740/P/23/002. Office of Chemical Safety and Pollution Prevention. Washington, DC. February 2023. <https://www.regulations.gov/document/EPA-HQ-OPPT-2022-0918-0009>.
34. U.S. EPA. Cumulative Impacts Research: Recommendations for EPA's Office of Research and Development. EPA 600/R-22/014a. Office of Research and Development. Washington, DC. September 30, 2022. <https://www.epa.gov/system/files/documents/2023-05/cumulative%20impacts%20research-final%20report-epa%20600-r-22-014a%20%2812%29.pdf>.
35. U.S. EPA. EJSCREEN: Environmental Justice Screening and Mapping Tool. <https://www.epa.gov/ejscreen>.
36. U.S. EPA. EnviroAtlas. <https://www.epa.gov/enviroatlas>.
37. U.S. EPA. Guidelines for Carcinogen Risk Assessment. EPA/630/P-03/001F. Risk Assessment Forum. Washington, DC. March 2005. <https://www.regulations.gov/document/EPA-HQ-OA-2007-0679-0001>.
38. U.S. EPA. Supplemental Guidance for Assessing Susceptibility from Early-Life Exposure to Carcinogens. EPA/630/R-03/003F. Risk Assessment Forum. Washington, DC. March 2005. [https://www.epa.gov/sites/default/files/2013-09/documents/childrens\\_supplement\\_final.pdf](https://www.epa.gov/sites/default/files/2013-09/documents/childrens_supplement_final.pdf).
39. U.S. EPA. Peer Review Handbook (4th Edition). EPA/100/B-15/001. Science and Technology Policy Council. Washington, DC. October 2015. [https://www.epa.gov/sites/default/files/2020-08/documents/epa\\_peer\\_review\\_handbook\\_4th\\_edition.pdf](https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf).
40. OMB. Final Information Quality Bulletin for Peer Review. **Federal Register**. (70 FR 2664, January 14, 2005). <https://www.govinfo.gov/content/pkg/FR-2005-01-14/pdf/05-769.pdf>.
41. U.S. EPA. Draft Risk Evaluation for C.I. Pigment Violet 29 (Anthra[2,1,9-def:6,5,10-d'e'f]diisoquinoline 1,3,8,10(2H,9H)-tetrone) CASRN: 81-33-4. 740R18015. Office of Chemical Safety and Pollution Prevention. Washington, DC. November 2018. <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0604-0007>.
42. U.S. EPA. Draft Supplemental Analysis to the Draft Risk Evaluation for 1,4-Dioxane. EPA-740-R1-8007. Office of Chemical Safety and Pollution Prevention. November 2020. <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0067>.
43. TSCA Science Advisory Committee on Chemicals. Peer Review for EPA Draft Risk Evaluation for 1,4-Dioxane and Cyclic Aliphatic Bromide Cluster (HBCD). Meeting Minutes and Final Report No. 2019-02. October 2019. <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0063>.
44. Comments submitted to EPA in response to Notice of Availability on U.S. EPA. Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances; Proposed Rule. <https://www.regulations.gov/document/EPA-HQ-OPPT-2019-0238-0063>.

- [www.regulations.gov/docket/EPA-HQ-OPPT-2016-0654/comments](http://www.regulations.gov/docket/EPA-HQ-OPPT-2016-0654/comments).
45. Safe Drinking Water Act. 42 U.S.C. 300f *et seq.*
  46. U.S. EPA. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity, of Information Disseminated by the Environmental Protection Agency. EPA/260R–02–008. Office of Environmental Information. Washington, DC. October 2002. [https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines\\_pdf\\_version.pdf](https://www.epa.gov/sites/default/files/2020-02/documents/epa-info-quality-guidelines_pdf_version.pdf).
  47. U.S. EPA. Application of Systematic Review in TSCA Risk Evaluations. EPA/740/P1/8001. Office of Chemical Safety and Pollution Prevention. May 2018. [https://www.epa.gov/sites/default/files/2018-06/documents/final\\_application\\_of\\_sr\\_in\\_tsc\\_a\\_05-31-18.pdf](https://www.epa.gov/sites/default/files/2018-06/documents/final_application_of_sr_in_tsc_a_05-31-18.pdf).
  48. National Academies of Sciences Engineering and Medicine. The Use of Systematic Review in EPA's Toxic Substances Control Act Risk Evaluations. The National Academies Press. Washington, DC. 2021. <https://doi.org/10.17226/25952>.
  49. U.S. EPA. (2021) Draft TSCA Systematic Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances: A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies (Version 1.0). EPA–D–20–031. Office of Chemical Safety and Pollution Prevention. Washington, DC. December 2021. <https://www.regulations.gov/document/EPA-HQ-OPPT-2021-0414-0005>.
  50. NRC. Review of EPA's Integrated Risk Information System (IRIS) Process. The National Academies Press. Washington, DC. 2014. <https://www.nap.edu/catalog/18764/review-of-epas-integrated-riskinformation-system-iris-process>.
  51. EDSTAC. Endocrine Disruptor Screening and Testing Advisory Committee, Final Report, Volume I–II. Washington, DC 1998. <https://www.epa.gov/scipoly/ospendo/pubs/edspoverview/finalrpt.htm>.
  52. U.S. EPA. Weight of Evidence in Ecological Assessment. EPA/100/R–16/001. Risk Assessment Forum. Washington, DC. December 2016. <https://nepis.epa.gov/Exe/ZyPURL.cgi?Dockey=P100SFXR.txt>.
  53. U.S. EPA. Endocrine Disruptor Screening Program (EDSP); Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing. Office of Chemical Safety and Pollution Prevention. Washington, DC. 2011. <https://www.regulations.gov/document/EPA-HQ-OPPT-2010-0877-0021>.
  54. U.S. EPA. ORD Staff Handbook for Developing IRIS Assessments (2022). EPA/600/R–22/268. Office of Research and Development. Washington, DC. [https://cfpub.epa.gov/ncea/iris\\_drafts/recordisplay.cfm?deid=356370](https://cfpub.epa.gov/ncea/iris_drafts/recordisplay.cfm?deid=356370).
  55. U.S. EPA. Tiered Data Reporting to Inform, Prioritization, Risk Evaluation, and Risk Management under TSCA. Office of Chemical Safety and Pollution

Prevention. <https://www.epa.gov/chemical-data-reporting/tiered-data-reporting-inform-prioritization-risk-evaluation-and-risk>. (Accessed May 31, 2023.)

## VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders>.

### A. Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is a “significant regulatory action” as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023). Accordingly, EPA submitted this action to the OMB for Executive Order 12866 review. Documentation of any changes made in response to the Executive Order 12866 review are documented in the docket. EPA prepared an analysis of the potential costs associated with this action. This analysis can be found in Unit VI.B.

### B. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* EPA has prepared a new rule-related Information Collection Request (ICR) document entitled “Procedures for Requesting a Chemical Risk Evaluation under TSCA (Proposed Rule)” and is identified by EPA ICR No. 2781.01, to replace an existing approved ICR. You can find a copy of the new ICR document (Ref. 4) in the docket for this rulemaking, and it is briefly summarized here.

The information activities related to the current requirements for manufacturer-requested risk evaluations are already approved by OMB in an ICR entitled, “Procedures for Requesting a Chemical Risk Evaluation under TSCA” (EPA ICR No. 2559.03 and OMB Control No. 2070–0202) (Ref 4). The proposed rule replacement ICR addresses the information collection requirements contained in the current regulations as well as in the amendments identified in this proposed rule. As addressed in the currently approved ICR and pursuant to 40 CFR part 702, subpart B, the information collection activities are those carried out by a chemical manufacturer in requesting a specific chemical risk evaluation under TSCA be conducted by EPA. EPA established the process for conducting risk evaluations under TSCA. Chemicals that will undergo this evaluation include chemicals

designated by the Agency as high-priority in accordance with 40 CFR part 702, subpart A, as well as chemicals for which EPA has granted requests made by manufacturers to have the chemicals evaluated under EPA's risk evaluation process. The replacement ICR addresses proposed amendments to information requirements for manufacturer-requested risk evaluations, including proposed amendments to information requirements addressing joint submissions, the scope of the requested risk evaluation, and the information to be provided in support of the requested risk evaluation, and fee payment. Please see Unit III.K. for additional information about these proposed amendments.

The replacement ICR addresses adjustments to the estimated number of respondents, time for activities, and wage rates related to the current regulatory requirements as approved under OMB Control No. 2070–0202. In addition, the replacement ICR addresses program changes related to the proposed amendments, including changes to content requirements for manufacturer-requested risk evaluation request and associated process changes. The estimated annual burden approved by OMB under OMB Control No. 2070–0202 is 419 hours. The total estimated annual respondent burden being proposed in the replacement ICR is 166 hours, a net decrease of 253 hours. The primary driver in the burden decrease is the estimated number of responses dropping to 1 per year based on the number of requests EPA has received to date. Certain information included with a manufacturer-requested risk evaluation may be claimed as TSCA CBI in accordance with TSCA section 14 (15 U.S.C. 2613), and any such claims must be substantiated in accordance with the Act.

#### Respondents/affected entities:

Persons that manufacture chemical substances and request a chemical be considered for risk evaluation by EPA. Such persons may voluntarily request a risk evaluation but would be required to comply with the requirements for such a request. See Unit I.A.

#### Respondent's obligation to respond:

Voluntary (15 U.S.C. 2605(b)(4)).

Estimated number of respondents: 3.

Frequency of response: On occasion.

Total estimated burden: 166 hours (per year). Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$115,711 (per year), includes \$0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB

control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rulemaking. EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at <https://www.reginfo.gov/public/do/PRAMain>. Find this particular ICR by selecting "Currently under Review—Open for Public Comments" or by using the search function. OMB must receive comments no later than November 29, 2023.

#### *C. Regulatory Flexibility Act (RFA)*

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The small entities subject to the requirements of this action are manufacturers of chemical substances that submit requests to EPA seeking chemical risk evaluations. The Agency has determined that a low number of small entities may be impacted by voluntarily submitting a request to EPA for a chemical to undergo a risk evaluation. The 2017 final rule considered firms in 60 different NAICS codes that may choose to pursue a manufacturer-requested risk evaluation (approximately 30,000 firms) of which 76 percent were classified as small business (approximately 22,000 firms). When EPA promulgated the 2017 final rule, the Agency estimated that it would receive 5 MRRE submissions per year. However, manufacturers have submitted only 4 MRRE requests since 2017 (or less than one request per year, on average). Therefore, based on the number of submissions received by EPA since 2017, the Agency estimates it will receive only one manufacture-requested risk reevaluation per year. That is, only one out of approximately 22,000 small businesses is expected to choose to incur the submission costs (\$115,711) in any one year and, thus, a significant number of small businesses would not be impacted by this rulemaking. The decision to request a risk evaluation for a chemical is voluntary and manufacturers may decide not to make such a request. Details of this analysis are presented in the rule-related ICR.

#### *D. Unfunded Mandates Reform Act (UMRA)*

This action does not contain any unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. The costs involved in this action are imposed only on the private sector entities (manufacturers) that may voluntarily elect to submit a request for a risk evaluation as they would be required to comply with the proposed requirements for such requests.

#### *E. Executive Order 13132: Federalism*

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999) because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

TSCA section 18(c)(3) defines the scope of Federal preemption with respect to any final rule EPA issues under TSCA section 6(a). That provision provides that Federal preemption of "statutes, criminal penalties, and administrative actions" applies to "the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to [TSCA section 6(a)]." EPA reads this to mean that states are preempted from imposing requirements through statutes, criminal penalties, and administrative actions relating to any "hazards, exposures, risks, and uses or conditions of use" evaluated in the final risk evaluation and informing the risk determination that EPA addresses in the TSCA section 6(a) rulemaking. For example, Federal preemption applies even if EPA does not regulate in that final rule a particular COU, but that COU was evaluated in the final risk evaluation.

#### *F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments*

This action does not have tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Thus, Executive Order 13175 does not apply to this action.

#### *G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks*

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–201 of the Executive order. Therefore, this action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk. Since this action does not concern human health risks, EPA's Policy on Children's Health also does not apply. This procedural rule would address how EPA evaluates the risks of existing chemicals under TSCA, including potential risks to children and other PESS. EPA must initiate a rulemaking to address the unreasonable risk to human health or the environment that the Agency may determine are presented by a chemical substance as set forth in a TSCA risk evaluation. Although this procedural rule itself would not directly affect the level of protection provided to human health or the environment, EPA expects that this rulemaking would improve the Agency's consideration of risks to children and other PESS and, in turn, better inform the Agency's determination of whether a chemical substance presents an unreasonable risk of injury to health under its conditions of use. An EPA rulemaking to address an unreasonable risk of injury to health that the Administrator determines is presented by a chemical substance following a risk evaluation could qualify as a covered regulatory action under E.O. 13045 and could be subject to EPA's Policy on Children's Health.

#### *H. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use*

This action is not a "significant energy action" under Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not likely to have a significant adverse effect on the supply, distribution or use of energy and has not otherwise been designated by the Administrator of OMB's Office of Information and Regulatory Affairs as a "significant energy action."

*I. National Technology Transfer and Advancement Act (NTTAA)*

This proposed rulemaking does not involve technical standards. As such, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

*J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations and Executive Order 14096: Revitalizing Our Nation's Commitment to Environmental Justice for All*

EPA believes that it is not practicable to assess whether the human health or environmental conditions that exist prior to this action result in disproportionate and adverse effects on communities with environmental justice concerns consistent with Executive Order 14096 (88 FR 25251, April 26, 2023) and Executive Order 12898 (59 FR 7629, February 16, 1994). This action proposes revisions to the procedures that EPA will use to evaluate the risk of existing chemical substances pursuant to TSCA, and the Agency cannot foresee the final results of those evaluations. However, by specifically including overburdened communities in the regulatory definition of PESS, the Agency believes that this action would assist EPA and others in determining the potential exposures, hazards and risks to overburdened communities associated with existing chemicals a part of a TSCA risk evaluation. The proposed inclusion of overburdened communities among the PESS considered in a chemical risk evaluation would also enable the Agency to design appropriate risk management approaches to address the unreasonable risk that the Agency may determine is presented by a chemical, including any unreasonable risk that is disproportionately borne by communities with environmental justice concerns.

The information supporting this Executive order review is presented in Unit III.G.4.

**List of Subjects in 40 CFR Part 702**

Environmental protection, Chemicals, Chemical substances, Hazardous substances, Health and safety, Risk evaluation.

Dated: October 18, 2023.

**Michal Freedhoff,**

*Assistant Administrator, Office of Chemical Safety and Pollution Prevention.*

Therefore, for the reasons stated in the preamble, EPA proposes to amend 40 CFR part 702 as follows:

**PART 702—GENERAL PRACTICES AND PROCEDURES**

- 1. The authority citation for part 702 continues to read as follows:

**Authority:** 15 U.S.C. 2605 and 2619.

- 2. Revise and republish subpart B to read as follows:

**Subpart B—Procedures for Chemical Substance Risk Evaluations**

Sec.

- 702.31 General provisions.  
702.33 Definitions.  
702.35 Chemical substances subject to risk evaluation.  
702.37 Evaluation requirements.  
702.39 Components of risk evaluation.  
702.41 Peer review.  
702.43 Risk evaluation actions and timeframes.  
702.45 Submission of manufacturer requests for risk evaluations.  
702.47 Interagency collaboration.  
702.49 Publicly available information.

**Subpart B—Procedures for Chemical Substance Risk Evaluations**

**§ 702.31 General provisions.**

(a) *Purpose.* This subpart establishes the EPA process for conducting a risk evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

(b) *Scope.* These regulations establish the general procedures, key definitions, and timelines EPA will use in a risk evaluation conducted pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)) beginning [30 DAYS AFTER DATE OF PUBLICATION OF THE FINAL RULE IN THE **FEDERAL REGISTER**]. For risk evaluations initiated prior to this date, but not yet finalized, EPA will seek to apply the requirements in this subpart to the extent practicable. These requirements shall not apply retroactively to risk evaluations already finalized.

(d) *Categories of chemical substances.* Consistent with EPA's authority to take action with respect to categories of chemicals under 15 U.S.C. 2625(c), all references in this part to "chemical" or "chemical substance" shall also apply to "a category of chemical substances."

**§ 702.33 Definitions.**

All definitions in TSCA apply to this subpart. In addition, the following definitions apply:

*Act* means the Toxic Substances Control Act, as amended (15 U.S.C. 2601 *et seq.*).

*Aggregate exposure* means the combined exposures from a chemical substance across multiple routes and across multiple pathways.

*Conditions of use* means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.

*EPA* means the U.S. Environmental Protection Agency.

*Pathways* means the physical course a chemical substance takes from the source to the organism exposed.

*Potentially exposed or susceptible subpopulation* means a group of individuals within the general population identified by EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, the elderly, or overburdened communities.

*Reasonably available information* means information that EPA possesses or can reasonably generate, obtain, and synthesize for use in risk evaluations, considering the deadlines specified in TSCA section 6(b)(4)(G) for completing such evaluation. Information that meets the terms of the preceding sentence is reasonably available information whether or not the information is confidential business information, that is protected from public disclosure under TSCA section 14.

*Routes* means the ways a chemical substance enters an organism after contact, *e.g.*, by ingestion, inhalation, or dermal absorption.

*Sentinel exposure* means the exposure from a chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures.

*Uncertainty* means the imperfect knowledge or lack of precise knowledge of the real world either for specific values of interest or in the description of the system.

*Variability* means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population.

**§ 702.35 Chemical substances subject to risk evaluation.**

(a) *Chemical substances undergoing risk evaluation.* A risk evaluation for a chemical substance designated by EPA as a High-Priority Substance pursuant to

the prioritization process described in subpart A or initiated at the request of a manufacturer or manufacturers under § 702.45, will be conducted in accordance with this part, subject to § 702.31(c).

(b) *Percentage requirements.* EPA will ensure that, of the number of chemical substances that undergo risk evaluation under 15 U.S.C. 2605(b)(4)(C)(i), the number of chemical substances undergoing risk evaluation under 15 U.S.C. 2605(b)(4)(C)(ii) is not less than 25%, if sufficient requests that comply with § 702.37, and not more than 50%.

(c) *Manufacturer-requested risk evaluations for work plan chemical substances.* Manufacturer requests for risk evaluations, described in paragraph (a) of this section, for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments will be granted at the discretion of EPA. Such evaluations are not subject to the percentage requirements in paragraph (b) of this section.

#### § 702.37 Evaluation requirements.

(a) *Considerations.* (1) EPA will use applicable EPA guidance when conducting risk evaluations, as appropriate and where it represents the best available science.

(2) EPA will document that the risk evaluation is consistent with the best available science and based on the weight of the scientific evidence. Considerations for determining best available science shall include, but are not limited to, the following as applicable:

(i) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of the information;

(ii) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture;

(iii) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented;

(iv) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and

(v) The extent of independent verification or peer review of the information or of the procedures,

measures, methods, protocols, methodologies or models.

(3) EPA will ensure that all supporting analyses and components of the risk evaluation are suitable for their intended purpose, and tailored to the problems and decision at hand, in order to inform the development of a technically sound determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, based on the weight of the scientific evidence.

(4) EPA will not exclude conditions of use from the scope of the risk evaluation, but a fit-for-purpose approach may result in varying types and levels of analysis and supporting information for certain conditions of use, consistent with paragraph (b) of this section. The extent to which EPA will refine its evaluations for one or more condition of use in any risk evaluation will vary as necessary to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment.

(5) EPA will determine whether a chemical substance does or does not present an unreasonable risk after considering the risks posed under all of the conditions of use and, where EPA makes a determination of unreasonable risk, EPA intends to identify the conditions of use that significantly contribute to such determination.

(6) EPA will evaluate chemical substances that are metals or metal compounds in accordance with 15 U.S.C. 2605(b)(2)(E).

(b) *Information and information sources.* (1) EPA will base each risk evaluation on reasonably available information.

(2) EPA will apply systematic review and/or systematic approaches to reviewing reasonably available information that are objective, unbiased, and transparent.

(3) EPA may determine that certain information gaps can be addressed through application of assumptions, uncertainty factors, models, and/or screening to conduct its analysis with respect to the chemical substance, consistent with 15 U.S.C. 2625. The approaches used will be determined by the quality of reasonably available information, the deadlines specified in TSCA section 6(b)(4)(G) for completing the risk evaluation, and the extent to which the information reduces uncertainty.

(4) EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to obtain the information needed to perform a risk evaluation for a chemical

substance before initiating the risk evaluation for such substance. EPA will also use such authorities during the performance of a risk evaluation to obtain information as needed and on a case-by-case basis to ensure that EPA has adequate, reasonably available information to perform the evaluation. Where appropriate, to the extent practicable, and scientifically justified, EPA will require the development of information generated without the use of new testing on vertebrates.

(5) Among other sources of information, EPA will also consider information and advice provided by the Science Advisory Committee on Chemicals established pursuant to 15 U.S.C. 2625(o).

#### § 702.39 Components of risk evaluation.

(a) *In general.* Each risk evaluation will include all of the following components:

- (1) A Scope;
- (2) A Hazard Assessment;
- (3) An Exposure Assessment;
- (4) A Risk Characterization; and
- (5) A Risk Determination.

(b) *Scope of the risk evaluation.* The scope of the risk evaluation will include all the following:

(1) The condition(s) of use the EPA expects to consider in the risk evaluation.

(2) The potentially exposed populations, including any potentially exposed or susceptible subpopulations as identified as relevant to the risk evaluation by EPA under the conditions of use that EPA plans to evaluate.

(3) The ecological receptors that EPA plans to evaluate.

(4) The hazards to health and the environment that EPA plans to evaluate.

(5) A description of the reasonably available information and scientific approaches EPA plans to use in the risk evaluation.

(6) A conceptual model that describes the actual or predicted relationships between the chemical substance, its associated conditions of use through predicted exposure scenarios, and the identified human and environmental receptors and human and ecological health hazards.

(7) An analysis plan that includes hypotheses and descriptions about the relationships identified in the conceptual model and the approaches and strategies EPA intends to use to assess exposure and hazard effects, and to characterize risk; and a description, including quality, of the data, information, methods, and models, that EPA intends to use in the analysis and how uncertainty and variability will be characterized.

(8) EPA's plan for peer review consistent with § 702.41.

(c) *Hazard assessment.* (1) The hazard assessment process includes the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical substance under the conditions of use.

(2) Hazard information related to potential health and environmental hazards of the chemical substance will be reviewed in a manner consistent with best available science based on the weight of scientific evidence and all assessment methods will be documented.

(3) Consistent with § 702.37(b), information evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, biomonitoring and/or human clinical studies, ecological field data, read across, mechanistic and/or kinetic studies in a variety of test systems. These may include but are not limited to: toxicokinetics and toxicodynamics (e.g., physiological-based pharmacokinetic modeling), and computational toxicology (e.g., high-throughput assays, genomic response assays, data from structure-activity relationships, in silico approaches, and other health effects modeling).

(4) The hazard information relevant to the chemical substance will be evaluated for identified human and environmental receptors, including all identified potentially exposed or susceptible subpopulation(s) determined to be relevant, for the exposure scenarios relating to the conditions of use.

(5) The relationship between the dose of the chemical substance and the occurrence of health and environmental effects or outcomes will be evaluated.

(6) Hazard identification will include an evaluation of the strengths, limitations, and uncertainties associated with the reasonably available information.

(d) *Exposure assessment.* (1) Where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use will be considered.

(2) Exposure information related to potential human health or ecological hazards of the chemical substance will be reviewed in a manner consistent with best available science based on the weight of scientific evidence and all assessment methods will be documented.

(3) Consistent with § 702.37(b), information evaluated may include, but would not be limited to: chemical

release reports, release or emission scenarios, data and information collected from monitoring or reporting, release estimation approaches and assumptions, biological monitoring data, workplace monitoring data, chemical exposure health data, and exposure modeling.

(4) Chemical-specific factors, including, but not limited to physical-chemical properties and environmental fate and transport parameters, will be examined.

(5) The human health exposure assessment will consider all potentially exposed or susceptible subpopulation(s) determined to be relevant.

(6) Environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological receptors and the exposures considered, including populations and communities, depending on the chemical substance and the ecological characteristic involved.

(7) EPA will describe whether sentinel exposures under the conditions of use were considered and the basis for their consideration.

(8) EPA will consider aggregate exposures to the chemical substance, and, when supported by reasonably available information, consistent with the best available science and based on the weight of scientific evidence, include an aggregate exposure assessment in the risk evaluation, or will otherwise explain in the risk evaluation the basis for not including such an assessment.

(9) EPA will assess all exposure routes and pathways relevant to the chemical substance under the conditions of use, including those that are regulated under other Federal statutes.

(e) *Risk characterization*—(1) *Requirements.* To characterize the risks from the chemical substance, EPA will:

(i) Integrate the hazard and exposure assessments into quantitative and/or qualitative estimates relevant to specific risks of injury to health or the environment, including any potentially exposed or susceptible subpopulations identified, under the conditions of use.

(ii) Not consider costs or other non-risk factors;

(iii) Describe the weight of the scientific evidence for the identified hazards and exposures.

(2) *Summary of considerations.* EPA will summarize, as applicable, the considerations addressed throughout the evaluation components, in carrying out the obligations under 15 U.S.C. 2625(h). This summary will include, as appropriate, a discussion of:

(i) *Considerations regarding uncertainty and variability.* Information about uncertainty and variability in each step of the risk evaluation (e.g., use of default assumptions, scenarios, choice of models, and information used for quantitative analysis) will be integrated into an overall characterization and/or analysis of the impact of the uncertainty and variability on estimated risks. EPA may describe the uncertainty using a qualitative assessment of the overall strength and limitations of the data and approaches used in the assessment.

(ii) *Considerations of data quality.* A discussion of data quality (e.g., reliability, relevance, and whether methods employed to generate the information are reasonable for and consistent with the intended use of the information), as well as assumptions used, will be included to the extent necessary. EPA also expects to include a discussion of the extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies, or models used in the risk evaluation.

(iii) *Considerations of alternative interpretations.* If appropriate and relevant, where alternative interpretations are plausible, a discussion of alternative interpretations of the data and analyses will be included.

(iv) *Additional considerations for environmental risk.* For evaluation of environmental risk, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

(f) *Risk determination.* (1) As part of the risk evaluation, EPA will make a single determination as to whether the chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use.

(2) In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment. EPA will not consider exposure reduction

based on assumed use of personal protective equipment as part of the risk determination.

#### § 702.41 Peer review.

EPA expects that peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A), or portions thereof, will be consistent with the applicable peer review policies, procedures, guidance documents, and methods pursuant to guidance promulgated by Office of Management and Budget, EPA, and in accordance with 15 U.S.C. 2625(h) and (i).

#### § 702.43 Risk evaluation actions and timeframes.

(a) *Draft scope.* (1) For each risk evaluation to be conducted EPA will publish a document that specifies the draft scope of the risk evaluation EPA plans to conduct and publish a notice of availability in the **Federal Register**. The document will address the elements in § 702.39(b).

(2) EPA generally expects to publish the draft scope during the prioritization process concurrent with publication of a proposed designation as a High-Priority Substance pursuant to § 702.9(g), but no later than 3 months after the initiation of the risk evaluation process for the chemical substance.

(3) EPA will allow a public comment period of no less than 45 calendar days during which interested persons may submit comment on EPA's draft scope. EPA will open a docket to facilitate receipt of public comments.

(b) *Final scope.* (1) EPA will, no later than 6 months after the initiation of a risk evaluation, publish a document that specifies the final scope of the risk evaluation EPA plans to conduct, and publish a notice of availability in the **Federal Register**. The document shall address the elements in § 702.39(b).

(2) For a chemical substance designated as a High-Priority Substance under subpart A of this part, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(c) *Draft risk evaluation.* EPA will publish a draft risk evaluation, publish a notice of availability in the **Federal Register**, open a docket to facilitate receipt of public comment, and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation. The document shall include the elements in § 702.39(c) through (f).

(d) *Final risk evaluation.* (1) EPA will complete and publish a final risk evaluation for the chemical substance

under the conditions of use as soon as practicable, but not later than 3 years after the date on which EPA initiates the risk evaluation. The document shall include the elements in § 702.39(c) through (f) and EPA will publish a notice of availability in the **Federal Register**.

(2) EPA may extend the deadline for a risk evaluation for not more than 6 months. The total time elapsed between initiation of the risk evaluation and completion of the risk evaluation may not exceed 3 and one half years.

(e) *Final determination of unreasonable risk.* Upon determination by the EPA pursuant to § 702.39(f) that a chemical substance presents an unreasonable risk of injury to health or the environment, EPA will initiate action as required pursuant to 15 U.S.C. 2605(a).

(f) *Final determination of no unreasonable risk.* A determination by the EPA pursuant to § 702.39(f) that the chemical substance does not present an unreasonable risk of injury to health or the environment will be issued by order and considered to be a final Agency action, effective on the date of issuance of the order.

(g) *Substantive revisions to scope documents and risk evaluations.* The circumstances under which EPA will undertake substantive revisions to scope and risk evaluation documents are as follows:

(1) *Draft documents.* To the extent there are changes to a draft scope or draft risk evaluation, EPA will describe such changes in the final document.

(2) *Final scope.* To the extent there are changes to the scope of the risk evaluation after publication of the final scope document, EPA will describe such changes in the draft risk evaluation, or, where appropriate and prior to the issuance of a draft risk evaluation, may make relevant information publicly available in the docket and publish a notice of availability of that information in the **Federal Register**.

(3) *Final risk evaluation.* For any chemical substance for which EPA has already finalized a risk evaluation, EPA will generally not revise, supplement, or reissue a final risk evaluation without first undergoing the procedures at § 702.7 to re-initiate the prioritization process for that chemical substance, except where EPA has determined it to be in the interest of protecting human health and the environment to do so, considering the statutory responsibilities and deadlines under 15 U.S.C. 2605.

(4) *Process for revisions to final risk evaluations.* Where EPA determines to

revise or supplement a final risk evaluation pursuant to paragraph (g)(3) of this section, EPA will follow the same procedures in this section including publication of a new draft and final risk evaluation and solicitation of public comment in accordance with §§ 702.43(c) and (d), and peer review, as appropriate, in accordance with § 702.41.

#### § 702.45 Submission of manufacturer requests for risk evaluations.

(a) *General provisions.* (1) One or more manufacturers of a chemical substance may request that EPA conduct a risk evaluation on a chemical substance.

(2) Such requests must comply with all the requirements, procedures, and criteria in this section.

(3) Subject to limited exceptions in paragraph (e)(7)(iii) of this section, it is the burden of the requesting manufacturer to provide EPA with the information necessary to carry out the risk evaluation.

(4) In determining whether there is sufficient information to support a manufacturer-requested risk evaluation, EPA expects to apply the same standard as it would for EPA-initiated risk evaluations, including but not limited to the considerations and requirements in § 702.37.

(5) EPA may identify data needs at any time during the process described in this section, and, by submitting a request for risk evaluation under this section, the requesting manufacturer agrees to provide, or develop and provide, EPA with information EPA deems necessary to carry out the risk evaluation, consistent with the provisions described in this subpart.

(6) EPA will not expedite or otherwise provide special treatment to a manufacturer-requested risk evaluation pursuant to 15 U.S.C. 2605(b)(4)(E)(ii).

(7) Once initiated in accordance with paragraph (e)(9) of this section, EPA will conduct manufacturer-requested risk evaluations following the procedures in §§ 702.37 through 702.43 and §§ 702.47 through 702.49 of this subpart.

(b) *Method for submission.* All manufacturer-requested risk evaluations under this subpart must be submitted via the EPA Central Data Exchange (CDX) found at <https://cdx.epa.gov>.

(c) *Content of request.* Requests must include all of the following information:

(1) Name, mailing address, and contact information of the entity (or entities) submitting the request. If more than one manufacturer submits the request, all individual manufacturers must provide their contact information.

(2) The chemical identity of the chemical substance that is the subject of the request. At a minimum, this includes: all known names of the chemical substance, including common or trades names, Chemical Abstracts Service (CAS) number, and molecular structure of the chemical substance.

(3) For requests pertaining to a category of chemical substances, an explanation of why the category is appropriate under 15 U.S.C. 2625(c). EPA will determine whether the category is appropriate for risk evaluation as part of reviewing the request in paragraph (e) of this section.

(4) A description of the circumstances under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of, and all information known to or reasonably ascertainable by the requesting manufacturer that supports the identification of the circumstances described in this paragraph (c)(4).

(5) All information known to or reasonably ascertainable by the requesting manufacturer on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), including but not limited to:

(i) The chemical substance's exposure potential, including occupational, general population and consumer exposures, and facility release information;

(ii) The chemical substance's hazard potential, including all potential environmental and human health hazards;

(iii) The chemical substance's physical and chemical properties.

(iv) The chemical substance's fate and transport properties including persistence and bioaccumulation;

(v) Potentially exposed or susceptible subpopulations which the manufacturer(s) believes to be relevant to the EPA risk evaluation;

(vi) Whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and the nearby drinking water source(s);

(vii) The chemical substance's production volume or significant changes in production volume; and

(viii) Any other information relevant to the hazards, exposures and/or risks of the chemical substance.

(6) Where information described in paragraph (c)(4) or (5) of this section is unavailable, an explanation as to why, and the rationale for why, in the requester's view, the provided information is nonetheless sufficient to

allow EPA to complete a risk evaluation on the chemical substance.

(7) Copies of all information referenced in paragraph (c)(5) of this section, or citations if the information is readily available from public sources.

(8) A signed certification that all information contained in the request is accurate and complete, as follows:

I certify that to the best of my knowledge and belief:

(A) The company named in this request manufactures the chemical substance identified for risk evaluation.

(B) All information provided in the request is complete and accurate as of the date of the request.

(C) I have either identified or am submitting all information in my possession and control, and a description of all other data known to or reasonably ascertainable by me as required under this part. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

(9) Where appropriate, information that will inform EPA's determination as to whether restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and that as a consequence the request is entitled to preference pursuant to 15 U.S.C. 2605(b)(4)(E)(iii).

(d) *Confidential business information.* Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B, and 40 CFR part 703.

(e) *EPA process for reviewing requests.* (1) *Public notification of receipt of request.* Within 15 days of receipt of a manufacturer-requested risk evaluation, EPA will notify the public that such request has been received.

(2) *Initial review for completeness.* EPA will determine whether the request appears to meet the requirements specified in this section (*i.e.*, complete), or whether the request appears to not have met the requirements specified in this section (*i.e.*, incomplete). EPA will notify the requesting manufacturer of the outcome of this initial review. For requests initially determined to be incomplete, EPA will cease review pending actions taken by the requesting manufacturer pursuant to paragraph (f) of this section. For requests initially determined to be complete, EPA will proceed to the public notice and comment process described in paragraph (e)(3) of this section.

(3) *Public notice and comment.* No later than 90 days after initially determining a request to be complete pursuant to paragraph (e)(2) of this

section, EPA will submit for publication the receipt of the request in the **Federal Register**, open a docket for that request and provide no less than a 60-day public comment period. The docket will contain the CBI sanitized copies of the request and all supporting information. The notice will encourage the public to submit comments and information relevant to the manufacturer-requested risk evaluation, including, but not limited to, identifying information not provided in the request, information the commenter believes necessary to conduct a risk evaluation, and any other information relevant to the conditions of use.

(4) *Secondary review for sufficiency.* Within 90 days following the end of the comment period in paragraph (e)(3) of this section, EPA will further consider whether public comments highlight deficiencies in the request not identified during EPA's initial review, and/or that the available information is not sufficient to support a reasoned evaluation. EPA will notify the requesting manufacturer of the outcome of this review. For requests determined to not be supported by sufficient information, EPA will cease review pending actions taken pursuant to paragraph (f) of this section. For requests determined to be supported by sufficient information, EPA will proceed with request review process in accordance with paragraph (e)(5) of this section.

(5) *Grant.* Where EPA determines a request to be complete and sufficiently supported in accordance with paragraphs (e)(2) and (4) of this section, and subject to the percentage limitations in TSCA section 6(b)(4)(E)(i)(II), EPA will grant the request. A grant does not mean that EPA has all information necessary to complete the risk evaluation.

(6) *Publication of draft conditions of use and request for information.* EPA will publish a notice in the **Federal Register** that identifies draft conditions of use, requests relevant information from the public, and provides no less than a 60-day public comment period. Within 90 days following the close of the public comment period in this paragraph, EPA will determine whether further information is needed to carry out the risk evaluation and notify the requesting manufacturer(s) of its determination, pursuant to paragraph (e)(7) of this section. If EPA determines at this time that no further information is necessary, EPA will initiate the risk evaluation, pursuant to paragraph (e)(9) of this section.

(7) *Identification of information needs.* Where additional information

needs are identified, EPA will notify the requesting manufacturer(s) and set a reasonable amount of time, as determined by EPA, for response. In response to EPA's notice, and subject to the limitations in paragraph (g) of this section, the requesting manufacturer(s) may:

(i) *Provide the necessary information.* EPA will set a reasonable amount of time, as determined by EPA, for the requesting manufacturer(s) to produce or develop and produce the information. Upon receipt of the new information, EPA will review for sufficiency and make publicly available to the extent possible, including CBI-sanitized copies of that information; or

(ii) *Withdraw the risk evaluation request.* Fees to be collected or refunded shall be determined pursuant to paragraph (k) of this section and 40 CFR 700.45; or

(iii) *Request that EPA obtain the information using authorities under TSCA sections 4, 8 or 11.* The requesting manufacturer(s) must provide a rationale as to why the information is not reasonably ascertainable to them. EPA will review and provide notice of its determination to the requesting manufacturer. Upon receipt of the information, EPA will review the additional information for sufficiency and provide additional public notice.

(8) *Unfulfilled information needs.* In circumstances where there have been additional data needs identified pursuant to paragraph (e)(7) of this section but the requesting manufacturer(s) is unable or unwilling to fulfill those needs in a timely manner, has produced information that is insufficient as determined by EPA, or where EPA determines that a request to use TSCA authorities under section 4, 8 or 11 is not warranted, EPA may deem the request to be constructively withdrawn under paragraph (e)(7)(ii) of this section.

(9) *Initiation of the risk evaluation.* Within 90 days of the end of the comment period provided in paragraph (e)(6) of this section, or within 90 days of EPA determining that information pursuant to paragraph (e)(7) of this section is sufficient, EPA will initiate the requested risk evaluation and follow all requirements in this subpart, including but not limited to §§ 702.37 through 702.43 and §§ 702.47 through 702.49 of this subpart, and notify the requesting manufacturer and the public. Initiation of the risk evaluation does not limit or prohibit the Agency from identifying additional data needs during the risk evaluation process.

(f) *Incomplete or insufficient request.* Where EPA has determined that a

request is incomplete or insufficient pursuant to paragraph (e)(2) or (4) of this section, requesting manufacturer(s) may supplement and resubmit the request. EPA will follow the process described in paragraph (e) of this section as it would for a new request.

(g) *Withdrawal of request.* Requesting manufacturer(s) may withdraw a request at any time prior to EPA's grant of such request pursuant to paragraph (e)(5) of this section, or in accordance with paragraph (e)(7) of this section and subject to payment of applicable fees. Requesting manufacturers may not withdraw a request once EPA has initiated the risk evaluation. EPA may deem a request constructively withdrawn in the event of unfulfilled information needs pursuant to paragraph (e)(8) of this section or non-payment of fees as required in 40 CFR 700.45. EPA will notify the requesting manufacturer and the public of the withdrawn request.

(h) *Data needs identified post-initiation.* Where EPA identifies additional data needs after the risk evaluation has been initiated, the requesting manufacturer(s) may remedy the deficiency pursuant to paragraph (e)(7)(i) or (iii) of this section.

(i) *Supplementation of original request.* At any time prior to the end of the comment period described in paragraph (e)(6) of this section, the requesting manufacturer(s) may supplement the original request with any new information that becomes available to the manufacturer(s). At any point prior to the completion of a manufacturer-requested risk evaluation pursuant to this section, manufacturer(s) must supplement the original request with any information that meets the criteria in 15 U.S.C. 2607(e) and this section, or with any other reasonably ascertainable information that has the potential to change EPA's risk evaluation. Such information must be submitted consistent with 15 U.S.C. 2607(e) if the information is subject to that section or otherwise within 30 days of the manufacturer's obtaining the information.

(j) *Limitations on manufacturer-requested risk evaluations—*

(1) *In general.* EPA will initiate a risk evaluation for all requests from manufacturers for non-TSCA Work Plan Chemicals that meet the criteria in this subpart, until EPA determines that the number of manufacturer-requested chemical substances undergoing risk evaluation is equal to 25% of the High-Priority Substances identified in subpart A as undergoing risk evaluation. Once that level has been reached, EPA will initiate at least one new manufacturer-

requested risk evaluation for each manufacturer-requested risk evaluation completed so long as there are sufficient requests that meet the criteria of this subpart, as needed to ensure that the number of manufacturer-requested risk evaluations is equal to at least 25% of the High-Priority substances risk evaluation and not more than 50%.

(2) *Preferences.* In conformance with § 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan chemicals in excess of the 25% threshold in § 702.35(b), EPA will give preference to requests for risk evaluations on chemical substances:

(i) First, for which EPA determines that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce, health or the environment; and then

(ii) Second, based on the order in which the requests are received.

(k) *Fees.* Manufacturers must pay fees to support risk evaluations as specified under 15 U.S.C. 2605(b)(4)(E)(ii), and in accordance with 15 U.S.C. 2525(b) and 40 CFR 700.45. In the event that a request for a risk evaluation is withdrawn by the requesting manufacturer pursuant to paragraph (g) of this section, the total fee amount due will be either, in accordance with 40 CFR 700.45(c)(2)(x) or (xi), 50% or 100% of the actual costs expended in carrying out the risk evaluation as of the date of receipt of the withdrawal notice. The payment amount will be determined by EPA, and invoice or refund issued to the requesting manufacturer(s) as appropriate.

#### § 702.47 Interagency collaboration.

During the risk evaluation process, not to preclude any additional, prior, or subsequent collaboration, EPA will consult with other relevant Federal agencies.

#### § 702.49 Publicly available information.

For each risk evaluation, EPA will maintain a public docket at <https://www.regulations.gov> to provide public access to the following information, as applicable for that risk evaluation:

(a) The draft scope, final scope, draft risk evaluation, and final risk evaluation;

(b) All notices, determinations, findings, consent agreements, and orders;

(c) Any information required to be provided to EPA under 15 U.S.C. 2603;

(d) A nontechnical summary of the risk evaluation;

(e) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation;

(f) Any final peer review report, including the response to peer review and public comments received during peer review; and

(g) Response to public comments received on the draft scope and the draft risk evaluation.

[FR Doc. 2023-23428 Filed 10-27-23; 8:45 am]

**BILLING CODE 6560-50-P**