UNITED STATES COURT OF APPEALS
FOR THE FIFTH CIRCUIT

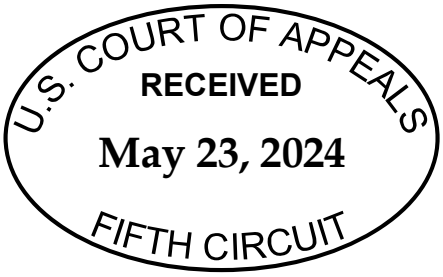
TEXAS CHEMISTRY COUNCIL and AMERICAN CHEMISTRY COUNCIL,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, and MICHAEL S. REGAN, Administrator, United States Environmental Protection Agency,

Respondents.



PETITION FOR REVIEW

Pursuant to the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2618, the Administrative Procedure Act, 5 U.S.C. § 706, and Rule 15 of the Federal Rules of Appellate Procedure, Petitioners Texas Chemistry Council and American Chemistry Council ("Petitioners") hereby petition this Court for review of the order of Respondent Michael S. Regan, the Administrator of Respondent United States Environmental Protection Agency ("EPA"), promulgating the final rule titled "Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)," which was published in the Federal Register on May 3, 2024, 89 Fed. Reg. 37,028 (May 3, 2024) ("Amended Risk Evaluation Rule"), and "issued" for purposes of judicial review on May 17, 2024. *See* 40 C.F.R. § 23.5(a); 15 U.S.C. § 2618(a)(2) (citing 28 U.S.C. § 2112).

Petitioners have attached a copy of the Amended Risk Evaluation Rule as Exhibit 1. The Amended Risk Evaluation Rule establishes the amended procedural framework that EPA will use to conduct risk evaluations to determine whether chemical substances present an unreasonable risk

of injury to health or the environment. Petitioners seek review of the Amended Risk Evaluation Rule pursuant to 15 U.S.C. § 2618(a)(1)(A), which authorizes any person, within 60 days of the promulgation of a rule under TSCA Subchapter I, to petition for review to the United States Court of Appeals for the circuit in which such person resides or in which such person's principal place of business is located. The principal place of business of Petitioner Texas Chemistry Council is located within this Circuit. Petitioner American Chemistry Council is not headquartered in a state within this Circuit, but pursuant to Federal Rule of Appellate Procedure 15(a)(1), its interests make joinder to this petition practicable.

Petitioners challenge the Amended Risk Evaluation Rule as arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law; in excess of statutory jurisdiction, authority, or limitations; and without observance of procedure required by law. *See* 15 U.S.C. § 2618(c)(1)(B) (providing that 5 U.S.C. § 706 shall apply to review of a rule under this section).

Respectfully submitted this 23rd day of May, 2024.

s/ Rafe Petersen
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CERTIFICATE OF INTERESTED PARTIES

The undersigned counsel of record certifies that the following listed persons and entities as described in the fourth sentence of Fifth Circuit Rule 28.2.1 have an interest in the outcome of this case. These representations are made in order that the judges of this court may evaluate possible disqualification or recusal.

- Texas Chemistry Council (Petitioner)
- American Chemistry Council (Petitioner)
- Holland & Knight LLP (Counsel for Petitioners)
- Rafe Petersen (Counsel for Petitioners)
- United States Environmental Protection Agency (Respondent)
- Michael S. Regan, Administrator, United States Environmental Protection Agency (Respondent)
- Merrick B. Garland, Attorney General, United States Department of Justice (Counsel for Respondents)

Petitioners Texas Chemistry Council and American Chemistry Council are trade associations and neither have parent corporations. No publicly held corporations have a 10% or greater ownership interest in either Petitioners Texas Chemistry Council and American Chemistry Council.

s/ Rafe Petersen
Rafe Petersen
HOLLAND & KNIGHT LLP
Attorney for Petitioners

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Fifth Circuit by using the appellate CM/ECF system on May 23, 2024. I certify that the below listed participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system. In addition, I transmitted a copy to the U.S. Environmental Protection Agency's Office of General Counsel by certified mail, return receipt requested to accomplish service pursuant to 28 U.S.C. § 2112 and 40 C.F.R. 23.12(a).

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I certify under penalty of perjury that the foregoing is true and correct.

Executed on 23rd day of May, 2024 in Washington, D.C.

s/ Rafe Petersen
Rafe Petersen
HOLLAND & KNIGHT LLP
Attorney for Petitioners

Exhibit 1

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA–HQ–OPPT–2023–0496; FRL–8529–02–OCSPP]

RIN 2070–AK90

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA or the Agency) is finalizing amendments to 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 reconsidered the procedural framework rule for conducting such risk evaluations and is revising certain aspects of that framework to better align with the statutory text and applicable court decisions, 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: This final rule is effective on July 2, 2024.

ADDRESSES: EPA has established a docket for this action under Docket ID No. EPA–HQ–OPPT–2023–0496. All documents in the docket are listed on the *https://www.regulations.gov* website. Although listed in the index, some information is not publicly available, *e.g.*, CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the internet and will be publicly available only in hard copy form. Publicly available docket materials are available electronically through *https://www.regulations.gov*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Susanna Blair, Immediate Office, Office of Pollution Prevention and Toxics (7401M), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–4371; email address: *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*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

EPA is amending procedural requirements that apply to the Agency's activities in carrying out TSCA risk evaluations. EPA is also amending the process and requirements that manufacturers (including importers) are 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 North American Industrial Classification System (NAICS) codes for entities that may be interested in or affected by this action. The following list of 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 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 promulgating this final rule 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. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983).

C. What action is the Agency taking?

EPA is amending 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 amending the process and requirements for manufacturers making a voluntary request for an Agency-conducted risk evaluation.

D. Why is the Agency taking this action?

As further explained in Units I., II., III. and IV., 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.

The Agency is amending the 2017 final rule as a result of this reexamination for the reasons explained elsewhere through the preambles of the proposed and final rules and the response to comments.

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 IV.J., which apply to manufacturers when manufacturers (including importers) elect to request that EPA perform a risk evaluation on a particular chemical substance. EPA estimated the potential burden and costs associated with the amended requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The estimates of burden and costs are available in the docket, and are discussed in Unit VII.B. 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 VII.B. Since the incremental impacts of this rule involve the activities that a manufacturer requesting a risk evaluation must perform, the estimated incremental costs to the public are expected to be negligible.

II. Background

The background for this rulemaking, including the statutory requirements for risk evaluation, the judicial review of the 2017 final rule, EPA's review of the 2017 final rule, and lessons learned from the Agency's implementation of the risk evaluation program are discussed in the notice of proposed rulemaking (Ref. 5 at pp. 74293 through 74294).

In response to public comments on the proposed rule and as described in Units III. and IV., EPA is making a number of changes in this final rule to provide additional clarification to EPA's process for conducting risk evaluations under TSCA. These include, among other changes, clarifications to: (1) Communications around which conditions of use are significantly contributing to a determination that a chemical substance presents unreasonable risk; (2) assumptions with respect to worker exposures and consideration of reasonably available information; (3) calculation of risk-based occupational exposure values in the risk evaluation; (4) EPA's commitment to conduct risk evaluations consistent with the "best available science" and based on the weight of the scientific evidence; (5) application of systematic review and methodological approaches consistent with those principles; (6) the process and requirements for manufacturer-requested risk evaluations; (7) EPA's potential identification of an overburdened community as a potentially exposed or susceptible subpopulation; and (8) peer review on TSCA risk evaluations.

EPA intends that the provisions of this rule be severable. While there may be provisions of this rule that are inextricably intertwined with other provisions, most of the provisions of this rule could function sensibly without particular invalidated provisions. Specifically, in many cases, the amendments to 40 CFR part 702 finalized in this rule involve separate elements of the risk evaluation process—or even separate processes all together—and EPA's decision to amend one portion of the rule was not dependent or reliant upon its decision to amend other portions of the rule. Especially because of the scope of the rule, it is not feasible to anticipate or address every permutation of this concept here. However, EPA has considered how the rule would function in various configurations and intends to preserve the rule to the fullest extent possible if any individual provision or part of this rule is invalidated.

To illustrate how various portions of this rule may be severable, EPA proffers the following two examples. First, if a court were to find flaw with a particular process provision (*e.g.*, a provision pertaining to publishing scope documents) and strike that provision, it would not prevent EPA in any way from looking to other process provisions (*e.g.*, a provision on soliciting peer review or on determining whether a chemical presents an unreasonable risk) in conducting its risk evaluations under this amended rule. While invalidating such provisions could perhaps be disruptive to ongoing risk evaluations, it would not prevent EPA from completing the rest of the evaluation consistent with both the remaining portions of the rule and its obligations under TSCA. Second, there are provisions that have little to no level of interrelation in this rule. For example, EPA's processes under this rule for conducting EPA-initiated risk evaluations and for reviewing manufacturer requests for risk evaluations are wholly independent and the invalidation of a provision (or even every provision) pertaining to one such process would not impact EPA's ability to rely on the remainder of the rule for the other process.

In additional to these examples, EPA notes that the ability of the various provisions of this rule to function sensibly without invalidated provisions is further illustrated by the history of the first 10 risk evaluations following the 2016 amendments to TSCA. Between 2016 and today, EPA has operated under the statutory mandate itself, the 2017 final rule (82 FR 33726), and the version of that rule that existed after *Safer Chemicals, Healthy Families* v. *EPA*, 943 F.3d 397 (9th Cir. 2019). Throughout this time, the risk evaluation process as a whole has continued to function sensibly even as EPA promulgated particular provisions and concepts through the 2017 rule and some of those provisions and concepts were subsequently vacated by the Ninth Circuit (*e.g.*, the applicability of criminal penalties, determinations on scientific standards, and the exclusion of legacy uses). For the forgoing reasons, EPA finds that the amendments in this final rule are generally severable.

III. Response to Public Comments

In response to the proposed rule, EPA received 30,434 public comments. EPA determined that 90 were unique and responsive to the request for comments (2 of which were form letter masters),

30,323 were copies of form letters, 11 were duplicates, and 10 were non-germane. The commenters included industry trade associations, advocacy organizations, a union, federal/state government agencies, a tribal council, academic institutions, and individuals. Major comments are discussed in the context of particular provisions in Unit IV. A more detailed discussion is provided in the Response to Comment Document for this rule and available in the docket (Ref. 6).

IV. Overview of Provisions in Final Rule

The purpose of this rulemaking is to update the risk evaluation process established in 40 CFR part 702, subpart B outlining 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 amendments to the procedural rule 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; (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. Improvements to the risk evaluation process in these proposed amendments will result in stronger scientific products that can support needed public health and environmental protections to limit exposure to dangerous chemicals.

To accomplish these objectives, EPA is making targeted changes to and clarifying the existing process by which the Agency evaluates risk from chemical substances for purposes of TSCA section 6. The amended procedural rule will ensure that the risk evaluation process and outcomes are both scientifically and legally defensible, and transparent, while allowing the Agency flexibility to adapt and keep pace with changing science as it conducts TSCA risk evaluations into the future.

A. General Provisions

EPA is finalizing the general provisions at 40 CFR 702.31 as proposed. As stated in the rule at 40 CFR 702.31(c), the procedures apply to all risk evaluations initiated 30 days after the date of the final rule or later. EPA received several comments regarding the applicability of the procedures to ongoing manufacturer-requested risk evaluations (MRREs). 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. For MRRE requests that EPA has already granted, for example, it would not be practicable to apply the new upfront processes that occur prior to granting requests, or the content requirements for incoming requests. EPA believes it will be practicable, however, to make a single determination of unreasonable risk on the chemical substance as contemplated in the law and codified in this rule.

Similarly, EPA is finalizing the minor clarification with respect to the applicability of this rule to risk evaluations on categories of chemical substances in 40 CFR 702.31(d). EPA received comments in support of this clarification, but also some comments that were more generally apprehensive of category approaches in risk evaluations. This rule does not prescribe how or whether the Agency will identify categories appropriate for prioritization and risk evaluation. The criteria for establishing categories are specified in TSCA section 26(c). If EPA does categorize chemicals as a category, EPA will provide, on a case-by-case basis, the justification for inclusion of the chemicals in a category. EPA fully recognizes the challenges and complexities associated with defining categories and carrying out risk evaluations on categories of chemical substances, and the need for its action and decisions to be consistent with the best available science. EPA also agrees that transparency on the rationale and approach will be important should the Agency prioritize a category of chemical substances for risk evaluation in the future. The intent of the rule is simply to clarify that the procedural framework for evaluating chemical substances also applies to risk evaluations on categories of chemical substances.

EPA is also finalizing removal of the currently codified regulatory text at 40 CFR 702.31(d) in accordance with the Ninth Circuit's vacatur and remand of this provision applying criminal penalties to the submission of inaccurate or incomplete information to EPA pursuant to a manufacturer-requested risk evaluation (Ref. 7).

B. Technical Corrections and Reorganization

The proposed rule reflected a number of minor updates and corrections and general organizational restructuring. Specifically, references to 15 U.S.C. 2605(b)(2)(A) were 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. 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). Additionally, 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 has reorganized the sequence and structure of regulatory provisions to 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. The Agency received very few comments on these changes and no commenter expressed confusion or decreased lack of clarity. Therefore, EPA carried these changes through into the final rule.

In addition, EPA made minor clarifying edits to the final rule at 40 CFR 702.35(b) regarding the number of allowable manufacturer-requested risk evaluations as compared to the number of ongoing EPA-initiated risk evaluations. Although this provision codifies the statutory requirement at 15 U.S.C. 2605(b)(4)(E)(i), EPA slightly modified the phrasing to make it easier for the reader to understand and follow.

C. Definitions

EPA is finalizing minor updates to definitions for "pathways," "routes," "aggregate exposure," and "sentinel exposure." The final rule also maintains the definitions for "act," "conditions of use," "reasonably available information," "uncertainty," or "variability"—all unchanged from the 2017 final rule.

EPA proposed to eliminate the codified definitions for "best available science" and "weight of scientific evidence." In the proposed rule, EPA explained that having codified definitions in the procedural rule for these scientific terms was both unnecessary and could inhibit the Agency's flexibility to quickly adapt to and implement advancing scientific practices and approaches. EPA received a number of comments on these proposed changes, including both support for and opposition to eliminating the codified definitions. Commenters who opposed generally expressed concern that elimination of

the definitions would reduce transparency and clarity about the scientific standards that EPA will apply in risk evaluations, and/or call into question whether EPA would still meet the scientific standards in the law. EPA can say with confidence that the Agency is fully committed to meeting the requirements in the law, and to being transparent in each risk evaluation with respect to how scientific information, technical procedures, measures, methods, protocols, methodologies, or models are being employed in a manner consistent with the best available science and how decisions are based on the weight of the scientific evidence, as required by 15 U.S.C. 2625(h) and (i). As such, EPA is finalizing the removal of these definitions from the codified regulatory text. Unit IV.H provides additional discussion of how EPA will ensure that TSCA risk evaluations are consistent with the best available science and based on the weight of the scientific evidence.

EPA also proposed changes to the definition of "potentially exposed or susceptible subpopulation" (PESS), which currently include "infants, children, pregnant women, workers or the elderly." Namely, EPA proposed to add the phrase "overburdened communities" to the list of other examples of PESS that EPA might identify like "infants, children, pregnant women, workers, or the elderly." EPA received a number of comments on the proposed changes to this definition. Many commenters supported the change, and EPA's authority to expand upon the illustrative list of examples Congress provided in the statutory definition. Others opposed the change, citing concerns that it reflects an intention by EPA to dramatically expand the scope of risk evaluations in ways that can't conceivably be completed within statutory deadlines. Others shared concern that the rule did not provide objective criteria regarding how EPA would go about identifying communities that are "overburdened." After considering the comments, EPA has determined to finalize the change to the PESS definition as proposed. As a primary matter, the addition of "overburdened communities" to this definition is not itself a determination. Rather, it's an example of a subpopulation that EPA may identify as a PESS in future risk evaluations, and it is reflective of the reality that—in addition to groups like children and pregnant women—there are communities of people that may experience disproportionate risks from chemicals due to greater exposure or susceptibility to environmental and health harms. EPA fully appreciates the enormity of its responsibilities under TSCA—meeting statutory deadlines while ensuring robust evaluations of risks to human health and the environment, including risks to the most vulnerable populations—and is mindful that meeting those challenges will require comprehensive approaches that are carried out in a fit-for-purpose manner. EPA is also committed to maximizing the transparency of its decisions—including the identification of PESS—and believes that the requirements in this rule will further all of these objectives. Additional discussion of EPA's expected implementation of statutory requirements related to PESS can be found in Unit IV.F.4.

D. Scope of TSCA Risk Evaluations

TSCA was amended in 2016 amidst a backdrop of tens of thousands of unreviewed existing chemical substances in commerce, with no mandate that EPA conduct any assessments to determine whether those existing chemicals present unreasonable risk of injury to health or the environment. The few assessments that EPA did undertake prior to 2016 were narrowly focused on specific uses of chemicals (*e.g.*, paint and coating removal, vapor degreasing, etc.). The 2016 amendments required EPA to systematically prioritize those tens of thousands 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)). In so doing, Congress recognized that comprehensive progress on evaluating tens 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. In the absence of comprehensive risk evaluations on chemical substances (*i.e.*, under an approach that considered only a subset of a chemical's uses or exposures), uncertainty as to whether EPA had fully addressed a chemical's unreasonable risk would fester, eroding public confidence in the safety of chemicals pervasive in our households, communities and the environment, and encouraging states to adopt a patchwork of regulatory measures to address chemical risks.

EPA's 2017 final rule left some ambiguities with respect to the scope of TSCA risk evaluations, including whether EPA has discretion to exclude conditions of use or exposure pathways, the limits of EPA's discretion to determine what constitutes the conditions of use for a particular chemical, and what other flexibilities that EPA may have in its analytical approaches to ensure that comprehensive risk evaluations can still be completed within Congress' aggressive statutory deadlines. EPA proposed a number of important clarifications regarding the scope of TSCA risk evaluations that EPA believes will result in stronger scientific products that can support needed public health and environmental protections to address risks from dangerous chemicals. Those changes, a discussion of the public comments received, and EPA's approach for the final rule are discussed in the sections that follow.

1. *Inclusion of all conditions of use.* EPA proposed 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" (*e.g.*, the statement in 702.37(b)(4) that "EPA will not exclude conditions of use from the scope of the risk evaluation . . ."). As described in the proposed rule, EPA believes that the better reading of TSCA's statutory text and structure is that EPA lacks authority to exclude conditions of use from the scope of the risk evaluation. 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." Further, EPA believes the phrase "as determined by the Administrator" in the statutory definition of "conditions of use" means that EPA must apply fact and professional judgment in determining whether or not a particular circumstance is known, intended or reasonably foreseen—and should not be viewed as authority to select among those circumstances for inclusion or exclusion (15 U.S.C. 2602(4)).

A number of commenters supported EPA's proposed rule on this important

point. Of the commenters who opposed this change, several pointed to the language in TSCA section 6(b)(4)(D), which requires EPA to identify—as part of the risk evaluation scope—the hazards, exposures, and conditions of use that EPA "expects to consider." EPA believes this phrase is best read as directing the Agency to undertake a factual identification of the conditions of use associated with 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 does not interpret the "expects to consider" language in TSCA section 6(b)(4)(D) to allow EPA to pick and choose which exposures to include in a risk evaluation of a chemical substance. However, EPA has *some* discretion; the identification of a chemical's conditions of use falls squarely within EPA's purview and will necessarily involve the Agency applying both fact and professional judgment, particularly with respect to identifying whether a circumstance is reasonably foreseen. See Unit IV.D.2. EPA also has discretion in tailoring its level of analysis with respect to individual conditions of use within the scope of the risk evaluation and may choose to, for example, take a more qualitative approach to conditions of use that it determines are negligible contributors to exposures and risks based on the reasonable available information. EPA does not, however, view the statute as providing authority to categorically exclude known conditions of use or exposures from the scope of the risk evaluation entirely.

Contrary to some commenters' suggestions, EPA further believes that such a reading is consistent with Congressional intent. The purpose of the requirement to evaluate the "chemical substance" was to ensure that the Agency, through the TSCA 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. If EPA were to take the approach suggested by commenters and only evaluate a subset of a chemical's conditions of use, the existence of unevaluated uses and exposures would perpetuate uncertainties as to the safety of existing chemicals in the marketplace—the very problem Congress sought to address through its reform efforts.

Some commenters suggest that the Ninth Circuit's opinion in *Safer Chemicals, Healthy Families* v. *USEPA* (Ref. 2) affirmatively determined the issue of discretionary scoping authority, namely that EPA could permissibly consider only some conditions of use in TSCA risk evaluations. EPA disagrees; the Court did not state or imply as much anywhere in its opinion (Ref. 2). To the contrary, the Court held that the petitioners' challenge to the 2017 final rule on this point was not ripe for review because EPA had not yet finalized a risk evaluation that excluded conditions of use and the 2017 final rule text was ambiguous on whether EPA actually would do so. Separately, the Court was, however, unequivocal in striking down EPA's statements in the preamble to the 2017 final rule regarding its intention to categorically exclude "legacy uses" from TSCA risk evaluations, finding that such an approach "contradicts TSCA's plain language" directing EPA to evaluate risks from chemical substances under the conditions of use.

Several commenters characterized TSCA as a "gap filling" statute—regulating only exposures and conditions of use that are not adequately addressed under other statutes. Although EPA is familiar with the phrase from the legislative history of the original 1976 TSCA, it is not found anywhere within the statute—original or as amended—and has more recently been used in tandem with interpretive arguments to inappropriately narrow the scope of TSCA risk evaluations. EPA firmly rejected these arguments—that EPA should exclude conditions of use and exposure pathways from TSCA risk evaluations when those uses/exposures could be managed under the purview of another environmental statute—in the proposed rule at Unit III.E. Such an interpretation contradicts the plain language of the 2016 TSCA amendments directing EPA to, without caveat, evaluate risks from chemical substances under the conditions of use. EPA recognizes that there is a relevant statutory provision (*i.e.*, TSCA section 9) about whether risk *management* to address identified risks is better achieved under TSCA or another federal law. OCSPP is actively coordinating actions taken under TSCA with actions taken under other Federal laws administered by EPA. However, these risk management considerations cannot logically occur until after risks are identified in the TSCA risk evaluation process—not before or during—and are therefore inappropriate to use as a risk evaluation scoping mechanism.

Finally, as described in the proposed rule, 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. 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)). There may be situations where certain individual conditions of use are associated with relatively lower exposures, but when considered in aggregate contribute to unreasonable risk. Exclusion of conditions of use from risk evaluations—irrespective of the Agency's intention in so doing—may deprive the public of a complete picture of the chemical's risk, and prevent EPA from putting necessary protections in place to mitigate such risk to the general population or potentially exposed or susceptible subpopulations.

Risk evaluations that are comprehensive in scope—and therefore consistent with the law—may also need to be balanced with fit-for-purpose analytic approaches to keep the assessments manageable and able to be completed within the law's deadlines. EPA is committed to continuing to pursue and refine fit-for-purpose approaches in the context of individual risk evaluations in a manner that enables EPA to achieve Congress' goals for the protection of human health and the environment, while also completing its actions within statutory deadlines.

For these reasons, EPA is finalizing the changes to the rule ensuring EPA will not exclude conditions of use from consideration within the scope of TSCA risk evaluations.

2. *Determination of "conditions of use."* As described in the preamble to the proposed rule, EPA is distinguishing between the Agency's lack of discretion to exclude conditions of use as described in the previous section, and EPA's ability 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. For each risk evaluation, and consistent with the phrase "as determined by the Administrator" in the statutory definition of "conditions of use," EPA must analyze the reasonably available information and apply the facts, Agency expertise and professional judgment to determine that chemical's conditions of use.

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.

As described in the preamble to the proposed rule, there are a number of general categories of circumstances that are squarely conditions of use that generally must be included within the scope of TSCA risk evaluations, including "legacy use" and "associated disposal," production of a chemical as a byproduct, and the presence of a chemical as an impurity or within an article. Conversely, the Ninth Circuit opined that "legacy disposal" falls outside the definition of conditions of use. Likewise, EPA does not expect to consider "intentional misuse" of a chemical as a "condition of use," consistent with the legislative history (Ref. 8). EPA provided several examples in the proposed rule of how the Agency would analyze the reasonably available information to make the determination on conditions of use—particularly with respect to determining whether or not a circumstance is reasonably foreseen. EPA discussed, for example, weighing whether exposures from spills, leaks, accidents and climate-related impacts would be regular or predictable, versus those that are unsubstantiated, speculative or otherwise not likely to occur. A future one-time accident caused by an atypical one-time set of circumstances, for example, would likely not be considered "reasonably foreseen." EPA believes that this approach is consistent with the statutory text and structure, as well as Congressional intent.

EPA received a number of comments in this area, including support for considering chemical spills, accidents and other unplanned but foreseeable chemical releases and comments urging EPA to consider such scenarios on a more routine basis. Other commenters expressed concern that EPA did not articulate precise criteria or a standard for determining when a circumstance is reasonably foreseen. Consistent with the discussion in the proposed rule preamble, EPA maintains, however, that the determination of whether a particular circumstance is reasonably foreseen—and therefore an exposure that must be considered within the scope of the risk evaluation—is necessarily going to require a fact-specific, chemical-by-chemical analysis. Ultimately, EPA's determination on the chemical's conditions of use and the rationale to support those conclusions will be subject to public review and comment as part of each risk evaluation.

EPA also received comments that EPA should exclude so-called "de minimis" uses from consideration in risk evaluations—such as uses where a chemical may only be present in small amounts as an impurity or within an article. EPA disagrees, and maintains the position described in the preamble to the proposed rule. As described previously, relatively low exposures individually may contribute to unreasonable risk when considered in aggregate. Further, as EPA noted in the proposed rule, 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. Such uses may, however, be appropriate for more tailored or qualitative analyses—as supported by the reasonably available information and documented in the risk evaluation—allowing EPA to focus more detailed/intensive efforts on the conditions of use that pose the greatest potential for exposure and therefore risk. Although TSCA provides EPA with authority to "determine" the conditions of use, it does not provide EPA with discretion to exclude from the scope of risk evaluations known circumstances associated with the chemical (*e.g.*, legacy uses and associated disposal, production of the chemical as a byproduct, presence of the chemical in trace or de minimis amounts such as an impurity or within an article, etc.). Nonetheless, EPA expects to conduct risk evaluations in a fit-for-purpose manner, tailoring the level of analysis based on factors such as 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 to the environment; and other relevant considerations.

3. *Inclusion of all exposure pathways.* EPA also proposed regulatory changes to ensure that EPA will assess all exposure routes and pathways relevant to the chemical substance under the conditions of use. See 40 CFR 702.39(d)(9). As described in both the proposed rule and in Unit IV.D.1 of this rule, EPA does not interpret TSCA section 6(b)(4)(D) to provide authority to exclude conditions of use or exposure pathways from the scope of TSCA risk evaluations. Likewise, EPA proposed additional regulatory text to ensure that EPA would no longer 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 or under another Federal law administered by another agency. See 40 CFR 702.39(d)(9). EPA does not interpret TSCA section 9 to authorize exclusion of exposure pathways from TSCA risk evaluations.

A number of commenters supported EPA's interpretation that the plain language of the law requires the consideration of all relevant exposure pathways in TSCA risk evaluations. Commenters who opposed EPA's interpretation again pointed to the language in TSCA section 6(b)(4)(D), which requires EPA to identify—as part of the risk evaluation scope—the hazards, exposures and conditions of use that EPA "expects to consider." As described in Unit IV.D.1, EPA believes the law requires the Agency to factually identify relevant exposures associated with the chemical substance, while the "expects to consider" phrasing reflects the reality of the process: that the Agency's early expectations at the scoping phase may not always align perfectly with the conditions of use actually considered and assessed in the subsequent draft and final risk evaluations. For example, exposures that EPA initially expects to consider may change as EPA further considers and refines the reasonably available information during the risk evaluation process. In any event, EPA does not view the "expects to consider" language in TSCA section 6(b)(4)(D) as providing EPA with discretion to, for example, exclude known exposures.

Other commenters suggested that EPA's approach is inconsistent with Congress' intent. EPA disagrees. The law's requirement that EPA evaluate the "chemical substance" under the "conditions of use" 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. Further, it is only through this holistic approach to chemical risk evaluation that EPA will

be able to drive forward progress on the tens of thousands of unreviewed existing chemical substances in commerce. As described earlier in Unit IV.D.1, the 2016 TSCA reform efforts were designed to create more certainty and more confidence in the safety of existing chemicals in the marketplace. However, and contrary to Congress' goals, evaluating a subset of a chemical's exposures or conditions of use would only perpetuate uncertainties.

EPA further disagrees with commenters that argued consideration of a particular exposure pathway in a risk evaluation would conflict with or duplicate other regulatory programs. First, where another regulatory program has already assessed the risks from a chemical associated with a particular exposure pathway, EPA would necessarily consider this information—along with all other reasonably available information—as part of its evaluation under TSCA. Where unreasonable risk has been identified, EPA would consider, consistent with TSCA section 9, whether all or part of such risk might be more appropriately managed under another regulatory program implemented by EPA or another Federal agency. Consideration of an exposure pathway in a TSCA risk evaluation does not automatically mean that EPA will determine the chemical to present unreasonable risk or that EPA will propose regulatory requirements related to that particular exposure pathway. Nonetheless, EPA recognizes that intra- and interagency coordination is integral to ensuring that EPA actions are well-informed, effective, and efficient, and expects to continue and expand upon efforts to maximize such coordination moving forward.

Finally, EPA appreciates concerns expressed by some commenters that this approach could result in more complex and challenging risk evaluations. EPA disagrees, however, that considering all relevant exposure pathways in TSCA risk evaluations is a "missed opportunity" to streamline its assessments. As discussed, EPA concludes in this rule that the best interpretation of TSCA is that the law does not authorize the exclusion of relevant exposure pathways from consideration in a risk evaluation. EPA also observes that certain risk evaluations published by EPA during the prior Administration were challenged, including on the grounds that EPA's prior approach of excluding exposure pathways was inconsistent with the requirements of TSCA. The approach adopted in this rule may conserve judicial, EPA, and other federal government resources by avoiding or reducing the need for such litigation. In addition, EPA has discretion to carry out TSCA risk evaluations in a fit-for-purpose manner, tailoring the depth or extent of analysis commensurate with the nature and significance of the decision, and expects to employ these approaches to enable completion of risk evaluations within the statutory deadlines.

Accordingly, EPA is finalizing the changes in 40 CFR 702.39(d) as proposed to ensure that 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.

4. *Comprehensive but fit-for-purpose.* EPA noted in the preamble to the proposed rule that it does not believe risk evaluations under TSCA should 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 pursue risk evaluations in a manner that is otherwise incompatible with the statutory framework. The preamble to the proposed rule provided a discussion of how EPA expected to balance resource expenditure and manageability—namely by taking fit-for-purpose approaches that allow for varying types and levels of analysis.

Some commenters supported this discussion, while others shared reservations regarding whether fit-for-purpose approaches would ensure adequate consideration of risks from low-volume chemicals, and whether such approaches would meet the law's scientific standards in section 26. EPA fully recognizes that chemicals produced or used in low volumes may not mean that such chemicals present low risk, particularly with respect to persistent, bioaccumulative and toxic chemicals or aggregate exposure. Any fit-for-purpose approach in a risk evaluation on such chemicals would reflect this reality. Furthermore, EPA's fit-for-purpose approaches will be subject to notice and numerous opportunities for comment during the risk evaluation process. If a stakeholder believes, for example, that EPA's qualitative approach to assessing a particular condition of use or that its consideration of aggregate exposures is insufficient, EPA would welcome specific feedback in the context of that risk evaluation. EPA also agrees that it must adhere to the scientific standards in TSCA section 26 when making science-based decisions under TSCA section 6, including when conducting risk evaluations in a fit-for-purpose manner, and appreciates the suggestion that EPA consider developing guidance for how the Agency might apply fit-for-purpose approaches in different circumstances. EPA believes that fit-for-purpose approaches in risk evaluations are an essential part of implementing the TSCA program and sustaining it over the long-term.

5. *Additional efficiencies.* In the spirit of finding additional efficiencies to help EPA meet the aggressive timeframes in the law for completing risk evaluations, EPA sought comment on the idea of the Agency publishing and taking comment during prioritization on preliminary information to inform the scope of the potential risk evaluation—a process that could result in the publication of the "draft scope" before the initiation of a risk evaluation. EPA believes that a more sustainable process necessitates earlier—either before or during the prioritization process—review of reasonably available information, identification of data needs and gaps, and preliminary efforts to scope the potential risk evaluation. EPA did not propose to change the regulatory text requiring publication of a draft scope "no later than" three months after initiation, but described an approach where EPA would publish such 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.

Several commenters expressed support for this approach, noting that it could result in clearer scopes, more efficient risk evaluations, allow stakeholders to provide data earlier in the process, and increase the value of public engagement. Some commenters who opposed the approach argued that it was contrary to TSCA, which requires publication of the risk evaluation scope "not later than 6 months after the initiation of the risk evaluation." Others suggested that EPA instead provide a preliminary list of conditions of use during prioritization and make it available for public comment.

EPA notes that TSCA does not actually require the development of a draft scope. It is a regulatory requirement in the 2017 final rule (and maintained in this rule) designed to afford the public an opportunity to provide comment on the scope of the risk evaluation before it is finalized. EPA will continue to abide by the statutory requirement to publish the final scope within the first 6 months

after initiation of a risk evaluation. EPA has already been maintaining the practice of publishing a preliminary list of conditions of use during the Proposed Designation step of the prioritization process, as some commenters suggest. However, EPA sees additional value in publishing more robust preliminary information on the conditions of use, hazards, exposures and potentially exposed or susceptible subpopulations that the Agency expects to consider and any early indications as to how the Agency may apply fit-for-purpose approaches. Public comments received on this information can inform the final priority designation and, if the chemical is then designated as a high priority substance, the scope of the risk evaluation.

E. Risk Determinations

1. Single determination on the "chemical substance." EPA proposed to codify a requirement that EPA make a single risk determination on the chemical substance at the conclusion of the TSCA risk evaluation process, as opposed to individual risk determinations on each individual use of the chemical. As explained in the proposed rule, EPA believes that this approach reflects a plain reading of the statutory text and structure. EPA also believes that this approach is consistent with Congressional intent, and will enable the Agency's risk determinations to better reflect the potential for combined exposures across multiple conditions of use. 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." EPA views this language as requiring an evaluation on the chemical substance—not individual conditions of use—and for the evaluation to be based on the chemical's "conditions of use." As further described in the proposed rule, EPA explained its intention to continue to consider exposures associated with each condition of use, but to no longer make separate risk determinations.

EPA received comments supportive of this interpretation and its proposed codification, and others that disagreed with the interpretation. Commenters who disagreed with EPA's interpretation argued that the phrase "under the conditions of use" modifies the statutory directive in TSCA section 6(b)(4)(A) requiring EPA to determine "whether a chemical substance presents an unreasonable risk of injury to health or the environment" and that EPA could therefore not determine risks from a chemical substance independently from those conditions of use. EPA agrees that TSCA requires consideration of the chemical's conditions of use (*i.e.*, the intended, known and reasonably foreseen circumstances under which the chemical is manufactured, processed, distributed in commerce, used or disposed of) and that the potentially different exposure scenarios presented by different conditions of use should be reflected in the risk evaluation's exposure assessment. However, the plain language of the law requires EPA to determine whether the chemical substance, rather than individual conditions of use, presents an unreasonable risk. Moreover, the plain language instructs EPA to do so "under the conditions of use" (plural), not under each individual condition of use. As such, EPA's determination is based on analysis of the chemical's conditions of use—rather than on each condition of use "independently" as commenters would suggest. In addition to aligning EPA's process with the statutory text and structure, this approach ensures 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's interpretation is unchanged from the discussion in the proposed rule, and EPA is finalizing the regulatory text and conforming changes that ensure risk evaluations will always culminate in a single risk determination on the "chemical substance," including the language in 40 CFR 702.37(a)(5) and 40 CFR 702.39(f)(1).

2. *Risk communication related to single risk determination.* EPA is aware of concerns that a single risk determination on the chemical substance—especially where only certain uses are contributing to that determination—could lead to public confusion regarding the chemical's risks. EPA believes these risk communication issues are addressable, and it is a priority area the Agency is committed to improve upon. As a start, EPA is no longer referring to this as a "whole chemical" approach, as the Agency believes that phrase may be misinterpreted. A single 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. Where one or more conditions of use for the chemical present an unreasonable risk, the chemical substance itself necessarily presents an unreasonable risk. EPA is committed to being clearer in its communications on this point, including what to expect during risk management as described in the next section. To provide some additional assurances, EPA proposed regulatory text at 40 CFR 702.37(a)(5) that states: ". . . where EPA makes a determination of unreasonable risk, EPA intends to identify the conditions of use that significantly contribute to such determination."

Commenters nonetheless continued to express concern that the single risk determination would result in EPA determining that every chemical presents unreasonable risk, and ultimately create confusion within the general public regarding which uses of a chemical do or do not present risk. EPA appreciates the concerns regarding clear risk communication as part of each risk determination but disagrees with the suggestion that the single risk determination approach will lead to a finding of unreasonable risk in every instance. EPA does not pre-determine the outcome of any risk evaluation activity. Likewise, the law does not provide for or guarantee a particular risk determination outcome either.

In response to these comments, EPA is strengthening its commitment in the final rule to identify which conditions of use are significant contributors to the unreasonable risk by changing the text to indicate a more affirmative "will identify" from the proposed "intends to" and by moving the regulatory text directly into the section on the "Unreasonable Risk Determination" at 40 CFR 702.39(f). While not necessarily a perfect indicator of how EPA will ultimately regulate to address unreasonable risk, this communication should give industry stakeholders significant insight and more certainty. Additionally, the process for developing risk management rules under TSCA provides numerous opportunities for public and stakeholder engagement, and allows EPA to consider existing risk management controls and approaches. In addition to providing a rationale and explanation in the risk determination itself, the Agency is further committed to clearly communicating on the Agency's analysis of particular uses in other venues, and will refrain from making unqualified statements about the risk associated with the chemical substance that could generate the type of confusion commenters are concerned about.

EPA would caution, however, on placing too much emphasis on

communicative value of the risk determination itself. 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 on the regulatory actions needed to address any identified unreasonable risk 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.

3. *Regulatory approaches based on single risk determination.* Several commenters suggested that EPA will use a singular risk determination to regulate in an overly broad manner, creating unnecessary and duplicative requirements, and shifting the burden to industry to demonstrate that they should not be regulated.

An unreasonable risk determination on the chemical substance does not mean that EPA will regulate all conditions of use for that chemical, and EPA disagrees with commenters' suggestion to the contrary. To be clear: a single risk determination on the chemical substance will not increase regulatory burden. The determination itself (*i.e.*, "EPA has determined that 'chemical x' presents an unreasonable risk . . .") has no bearing on which conditions of use EPA will focus on during the risk management phase. 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)). The basis for EPA to determine the extent of necessary regulation in this context comes from the entirety of the risk evaluation—not simply the risk determination. Take for example, a scenario where an unreasonable risk is driven by just a few conditions of use, and EPA determines that such risk can be eliminated through regulations that apply narrowly to just those conditions of use. EPA would expect to target its risk management approaches accordingly and would not apply requirements more broadly. Further, a single risk determination on the chemical substance does not shift burdens from EPA to industry. It remains EPA's burden to provide the scientific support for any proposed and final rules to address unreasonable risk, and to demonstrate how such proposed action is necessary to address the unreasonable risk identified in the risk evaluation.

EPA also strongly disagrees that a single risk determination on the chemical substance would be unscientific or arbitrary. EPA's basic methodological approach to risk assessments is unchanged in this rule. For every chemical, EPA will, using the best available science and based on the weight of scientific evidence, conduct a hazard assessment, conduct an exposure assessment based on the chemical's conditions of use, characterize the risks, propose a determination as to whether the risk is unreasonable under TSCA, and conduct a transparent and independent scientific peer review with opportunities for public comment. The process itself is embodied in this procedural framework rule and has been subject to public notice and comment, as will each individual draft risk evaluation.

4. *Preemption of state laws/regulations.* EPA received comments suggesting that making a single risk determination on a chemical substance would undermine Congress' intent with respect to the state preemption provisions in TSCA section 18. Some commenters suggest that this risk determination approach—coupled with the belief that it would result in a determination of unreasonable risk in every case—would either effectively eliminate the possibility of preemption for specific conditions of use that do not present an unreasonable risk or alter the scope of preemption applied. Some commenters also note that EPA's approach results in a delay in application of permanent preemption. Specifically, commenters point out that a "no unreasonable risk" determination for a particular condition of use under commenters' approach could lead to a section 6(i)(1) determination triggering permanent preemption sooner than under EPA's approach. As a result, under EPA's approach, commenters suggest that state-specific approaches to regulating chemicals will increase during that delay time, resulting in the patchwork of state regulations that Congress sought to address in the 2016 amendments.

Commenters have a fundamental misunderstanding of EPA's interpretation of TSCA section 18 as it relates to preemption. Even if one were to accept commenters' hypothesis that a single risk determination would lead to a determination of unreasonable risk in every case (which EPA rejects), such an approach does not eliminate preemption or otherwise make any aspect of TSCA section 18 superfluous for conditions of use EPA addresses in its risk evaluation. First, pause preemption under section 18(b) applies only during the risk evaluation process and is entirely unaffected by how EPA frames its risk determination at the conclusion of that process. Permanent preemption is triggered under section 18(a)(1)(B)(ii) if EPA issues first a scope of the risk evaluation under section 6(b)(4)(D) and then a section 6(a) final rule or section 6(i)(1) determination based on the risk evaluation. The scope of this preemption is addressed in section 18(c)(3) and EPA reads this provision to apply permanent preemption to any condition of use within the scope of the risk evaluation which is the support document for any resulting section 6(a) rule or section 6(i)(1) determination. In the context of a section 6(a) rule, this is the case irrespective of whether those uses contribute to the unreasonable risk and/or are targeted for risk management. Thus, the scope of permanent preemption is the same under either a single risk determination for the chemical substance or the use-based approach previously applied. Consequently, while EPA disagrees with commenters' reading of TSCA with respect to the requirement for a single risk determination on the chemical substance, EPA agrees with commenters that Congress intended permanent preemption to apply to conditions of use EPA addresses in the risk evaluation.

The real distinction between the risk determination approaches is not whether preemption will occur or the scope of that preemption, but when (since, under the prior use-based approach, an order of no unreasonable risk could precede a rulemaking on other uses that do present unreasonable risk). EPA is not persuaded that such difference will result in a patchwork of unworkable and confusing requirements among the states as claimed by commenters. It is entirely speculative—and quite unlikely in EPA's view—to suggest that multiple States will seek to inconsistently regulate a particular chemical or certain conditions of use for a particular chemical during such a short period of time, *i.e.*, after issuance of the risk determination when pause preemption ceases and prior to the effective date of a TSCA section 6(a) rule when permanent preemption

applies, while EPA actively works to finalize a comprehensive national approach to risk management for that same chemical.

Regardless, as explained in Unit IV.E.1., EPA has concluded that the chemical-based approach to risk determination is required under a plain reading of the statutory text and structure and consistent with Congressional intent. EPA further notes, as described in the proposed rule, that the plain language in TSCA section 18 also supports the view that Congress intended EPA to make a single risk determination on the chemical substance, namely, the numerous references to "chemical substance" as opposed to uses of a chemical substance, and "determination" in the singular.

5. *"Unreasonable risk" considerations.* Neither TSCA nor this 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. The proposed rule included a discussion of considerations EPA may weigh in determining unreasonable risk, 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 potentially exposed or susceptible subpopulations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties. Additionally, the proposed rule includes a discussion of how EPA will also consider, where relevant, the Agency's analyses on aggregate exposures and cumulative risk in its risk determinations. EPA also proposed to codify at 40 CFR 702.39(f)(1) the statutory requirement to consider the risks to potentially exposed or susceptible subpopulations as part of its risk determination on a chemical substance. EPA did not receive significant comments on this topic and is finalizing this rule as proposed.

F. Risk Evaluation Considerations

1. *Occupational exposure assumptions.* EPA proposed new regulatory text at 40 CFR 702.39(f)(2) to ensure that "consideration of occupational exposure scenarios will take into account reasonably available information" and that EPA will "not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination." As described in the proposed rule, EPA had previously 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. However, EPA believes that the assumed use of PPE in a risk determination could lead to an underestimation of the risk to workers. For example, as described in the proposed rule, 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, the PPE is not sufficient to address the risk from the chemical, or their PPE does not fit or function properly. Many of OSHA's chemical-specific permissible exposure limits were adopted in the 1970s and have not been updated since they were established (Ref. 9). 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. The proposed addition would codify EPA's more recent practices and ensure fulsome consideration of exposure and risks to workers as part of TSCA risk evaluations.

A number of commenters strongly supported EPA's proposed changes, arguing that EPA's previous approach was inconsistent with the law. Others disagreed, stating that the proposed changes would result in overestimates of worker exposures, inaccurate risk determinations, and overly restrictive risk management actions. EPA recognizes that many companies likely have well-established occupational control measures in place. EPA has, in various contexts, received public comments from industry 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 would emphasize that the proposed rule states "in determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information. . . ." Where information on known occupational control measures is made available, the Agency is committed to taking that information into account in the exposure assessment. EPA has been consistent in urging industry to provide the Agency with information regarding worker exposure controls. Information from the risk evaluation's exposure assessment is also considered in risk management action and can be useful in facilitating consistency with broader industry best practices where possible. EPA encourages commenters to continue engaging with EPA on this point on chemical-specific actions and to provide the Agency with timely and relevant data that can be considered during the TSCA process.

Other commenters took issue with what they characterized as EPA's lack of support for an assumption that workers disregard PPE requirements, or that there is widespread noncompliance with OSHA. EPA disagrees with these characterizations. The proposed change in this rule is that EPA will not "assume use" of PPE for purposes of the risk determination—not that EPA will assume no use of PPE. Likewise, EPA is not asserting there is widespread noncompliance with OSHA requirements. As described earlier, EPA's exposure assessment on each chemical will be informed by the reasonably available information, and EPA encourages companies to submit information on their occupational exposure control practices, including the extent to which those practices may be standard for an industry, and any associated support. Further, EPA distinguishes "assumed use" of PPE from 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, fit, and effectiveness of PPE (*e.g.*, information demonstrating that performance of a condition of use is impossible in the absence of PPE), EPA would expect to take that information into account in the risk determination.

A number of commenters also argue that the proposed changes in the TSCA risk evaluation process would result in TSCA risk management efforts that duplicate or confuse OSHA standards. EPA's development of risk management rules under TSCA is a separate process that provides numerous opportunities for public engagement, and allows EPA to consider existing risk management controls and approaches to avoid or

minimize regulatory overlap or duplication. EPA rejects the notion that Congress provided OSHA with exclusive jurisdiction over worker safety. Congress explicitly directs EPA to evaluate and manage chemical risks to workers in TSCA. Although EPA has not suggested that OSHA is not meeting its own statutory requirements, OSHA itself acknowledges the limits of its authority to regulate exposures to hazardous chemicals. For example, and as described more in the proposed rule, OSHA lacks direct jurisdiction over state and local government workers, and does not cover self-employed workers, military personnel, and uniquely military equipment, systems, and operations, and workers whose occupational safety and health hazards are regulated by another Federal agency (for example, the Mine Safety and Health Administration, the Department of Energy, or the Coast Guard). EPA coordinates with OSHA on TSCA actions on a regular basis. Where unreasonable risk to workers has been identified, EPA would consider, consistent with TSCA section 9, whether such risk might be more appropriately managed under another regulatory program implemented by EPA or another Federal agency.

Similarly, EPA disagrees that the proposed changes regarding worker PPE assumptions would duplicate or confuse existing standards in other industries. Where stakeholders have information that demonstrates effective occupational exposure control practices for the chemical undergoing risk evaluation—whether through implementation of regulatory requirements imposed by other Agencies or in keeping with the standards of a particular industry—EPA encourages submission of that information to inform both the risk evaluation and risk management processes.

After consideration of these comments, EPA is finalizing the regulatory text at 40 CFR 702.39(f)(2) as proposed. However, and to further emphasize EPA's commitment to consider reasonably available information with respect to occupational exposure control practices as part of the risk evaluation, EPA is finalizing additional regulatory text to that effect in the exposure assessment section at 40 CFR 702.39(d). As described in Unit IV.F.5., EPA is further committing to make publicly available any risk-based occupational exposure values calculated as part of the risk evaluation.

2. *Aggregate exposure.* The proposed rule included regulatory text committing the Agency to consider aggregate exposures as part of TSCA risk evaluations and, when supported by reasonably available information, consistent with the best available science and based on the weight of scientific evidence, to include an aggregate exposure assessment in the risk evaluation, or otherwise explain the basis for not doing so. See 40 CFR 720.39(d)(8). EPA also proposed minor revisions to the definition of "aggregate exposure." These changes relate to the implementation of TSCA section 6(b)(4)(F)(ii), which provides that 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." These changes are consistent with the definition used in *General Principles for Performing Aggregate Exposure and Risk Assessments* (Ref. 10).

Several commenters expressed support for this change and offered additional suggestions to strengthen the requirement. Other commenters, while supportive of consideration of aggregate exposure generally, shared some concerns that aggregate exposure assessments may extend the time it will take EPA to complete a risk evaluation. Still other commenters argue that consideration of aggregate exposure will unnecessarily complicate risk evaluations and prevent the Agency from meeting its statutory deadlines. These comments reflect two broad competing challenges for EPA: how to carry out robust risk evaluations that capture the full extent of risks faced by communities—including risks from aggregate exposures—that will position EPA to protect against those risks, and how to keep those processes manageable in order to meet clear statutory requirements and deadlines set by Congress and to actually provide protections via risk management.

EPA believes the consideration of an aggregate exposure assessment may be particularly important to characterize and assess 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, exposure via drinking water and water recreation, and/or exposure via occupation-related activities) and/or from multiple sources (*e.g.*, through different conditions of use occurring at multiple nearby facilities or from multiple products), the Agency has clear authority to aggregate those exposures, subject to the scientific standards in TSCA section 26. Furthermore, in developing a comprehensive risk estimate for a chemical substance, it is the Agency's responsibility, when supported by the best available science, to consider the aggregation of individual exposures from individual conditions of use as well as consider aggregate exposure from multiple routes of exposure that may contribute to unreasonable risk. As described in the proposed rule, it may be appropriate to consider potential background exposures from non-TSCA uses that are not within the scope of the risk evaluation as part of an aggregate exposure assessment. Likewise, EPA could consider the disproportionate impacts that background exposures may have on overburdened communities to inform the final unreasonable risk determination.

On the other hand, EPA is mindful that Congress did not intend for TSCA risk evaluations to take longer than the 3.5 years allotted in the statute. Aside from just meeting legal responsibilities, staying within statutory deadlines also allows EPA to keep pace on working through the tens of thousands of unreviewed existing chemicals and propose/finalize rules to afford meaningful protections for human health and the environment.

EPA believes the proposed rule strikes the appropriate balance on considering aggregate exposures in TSCA risk evaluations, and, after considering public comments on this issue, is finalizing the new regulatory text as proposed.

3. *Cumulative risk.* Although EPA did not propose any regulatory changes regarding consideration of cumulative risk, advancing the science of cumulative risk is a high priority for the Agency to inform EPA's effort to better understand and mitigate risks to potentially exposed and susceptible subpopulations. In the preamble to the proposed rule, EPA noted that the best available science may indicate that the development of a cumulative risk assessment—looking at the combined health risk from multiple chemicals—is appropriate to ensure that risk to human health and the environment is adequately characterized. EPA further noted that TSCA provides 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)). EPA sought comment on how the Agency could incorporate provisions for cumulative risk assessment into the 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 what

Congress envisioned when it established deadlines for conducting risk evaluations.

Some commenters offered support for EPA's discussion on cumulative risk assessment as well as suggestions for going further, such as including a definition of "cumulative risk" in the rule. Another commenter cautioned against qualitative fit-for-purpose approaches undermining EPA's ability to effectively carry out a cumulative risk assessment. Another commenter, while supportive of advancing the science on cumulative risk assessment, shared concern about such an approach preventing EPA from timely completing risk evaluations and proposing necessary regulatory protections. Other commenters opposed consideration of cumulative risk. A number of commenters suggested that provisions requiring consideration of cumulative risk would further delay completion of risk evaluations. Others argued that such considerations are not allowable under TSCA.

EPA appreciated the range of perspectives shared by commenters. With respect to the comment that EPA should define cumulative risk in the regulatory text, EPA is not inclined to do so at this time, as there is no mention of "cumulative risk" in the rule or the law that would warrant a codified definition. EPA did, however, describe cumulative risk assessment in the preamble to the proposed rule, and has defined the phrase in "EPA's Framework for Cumulative Risk Assessment" (Ref. 11). EPA expects to continue to develop robust methodology for the inclusion of cumulative risk assessment in TSCA risk evaluations, and to continue to engage with stakeholders as part of that process. EPA believes that quantitative analyses may be necessary to support cumulative risk assessments, and will consider the appropriate analyses carefully when developing and pursuing any fit-for-purpose approaches. EPA disagrees with the suggestion that cumulative risk assessment is not allowable under TSCA. As described in the proposed rule, TSCA requires that EPA 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)). 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. Finally, EPA again appreciates commenters' concerns regarding the potential for cumulative risk analyses to increase the complexity of TSCA risk evaluation and create challenges for the Agency to timely complete them. As described in Unit IV.D.4, EPA intends to apply fit-for-purpose approaches in risk evaluations to ensure completion within the statutory timeframes, while also building a robust scientific basis for the effective characterization and management of unreasonable risk to human health and the environment.

After considering these comments, EPA is finalizing this rule without an explicit requirement related to cumulative risk assessment. EPA is nonetheless committed to considering and applying cumulative risk assessment approaches for future chemicals undergoing risk evaluation, where supported by the reasonably available information and best available science.

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 potentially exposed or susceptible subpopulation (PESS) 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)). EPA codified the statutory definition in the 2017, noting at that time that TSCA does not further define "greater susceptibility" or "greater exposure" giving the Agency discretion to interpret these terms. As such, the law authorizes EPA to identify any subpopulation that may be at greater risk due to greater susceptibility or exposure, and, likewise, to identify additional subpopulations beyond those examples listed in the statute, as relevant to a risk evaluation.

In this rule, and as described in Unit IV.C., EPA proposed to amend the regulatory definition of PESS by adding the term "overburdened communities" to the list of example subpopulations. This additional term reflects the Agency's understanding and acknowledgment that a chemical substance may disproportionately expose and/or may disproportionately impact communities already experiencing disproportionate and adverse human health or environmental burdens. Such disproportionality can be as a result of greater exposure or vulnerability to environmental hazards, lack of opportunity for public participation, or other factors. Increased exposure or 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.

Many commenters supported this proposed change and agreed with EPA that the examples provided in the statutory definition were illustrative rather than limiting. Others urged EPA to go even further by either specifically defining "overburdened communities" or including additional factors in the definition of "potentially exposed and susceptible subpopulations" like the consideration of non-chemical stressors (Ref. 12) that may increase susceptibility. Other commenters opposed adding "overburdened communities" to the definition of PESS, arguing that EPA lacks authority to add additional criteria to the PESS definition beyond what's included in the law. A few commenters suggested that "overburdened communities" does not fit with the other types of groups provided as examples in TSCA because they refer to individuals rather than a subpopulation defined by its location or geographic proximity. Some commenters argued the term was too subjective and that EPA did not provide sufficient clarity in how it would identify such communities or quantify "overburdened."

EPA does not believe it is necessary to define "overburdened communities" as part of this rule. In the same way that EPA considers whether children or workers or the elderly are a PESS in the context of a specific risk evaluation, EPA will look to whether "overburdened communities" are subject to exposure or susceptibility greater than the general population. EPA does not intend this term to be confined to a location or geographic proximity, but would use reasonably available information for each chemical to determine the inclusion of specific communities. Those experiencing "greater exposure" could include individuals or communities experiencing higher levels of exposure to a chemical substance due to

geography (*e.g.*, fenceline communities in close proximity to facilities emitting air pollutants or living near effluent releases to water), unique exposure pathways that differ from those of the general population (*e.g.*, Tribal communities where reliance on subsistence fishing results in increased chemical exposure via ingestion), and/or aggregate exposure via multiple conditions of use (*e.g.*, a worker who lives in close proximity to facilities emitting air pollutants). As discussed in Unit III.G.4. of the proposed rule, communities with "greater susceptibility" could include communities that due to their proximity to a higher proportion of industrial emitters may be experiencing greater burden or those with an increased risk of experiencing an adverse effect due to one's lifestage or a pre-existing condition or circumstance (Ref. 5). Although EPA certainly agrees that non-chemical stressors can increase susceptibility to adverse health outcomes, EPA does not believe that including such specific factors within the PESS regulatory definition is necessary.

EPA disagrees with commenters that EPA lacks authority to add "overburdened communities" to the list of potential PESS examples. Congress' inclusion of "such as" in the statutory definition provides EPA with clear discretion to go beyond the statute's list of examples. EPA further disagrees that this addition is substantively changing the criteria for identification of PESS (*i.e.*, greater exposure or susceptibility and greater risk than general population). EPA believes that an "overburdened community" or those that may be disproportionately exposed or impacted by environmental harms, is clearly an example of a group that may frequently be at greater risk than the general population.

While EPA appreciates commenters' desire for more transparency on how "overburdened communities" might be identified and associated risks quantified, such rationale and transparency is already a necessary component of every risk evaluation. In identifying PESS more generally, EPA expects to engage the public throughout the TSCA prioritization and risk evaluation processes, and to work with other EPA offices. Currently available screening tools, such as EJSCREEN (Ref. 13) or EnviroAtlas (Ref. 14), and other tools may 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). EPA also continues to develop approaches for assessing the risk to communities at greater exposures to chemical emissions. For example, EPA developed a screening level methodology to evaluate the potential chemical exposures and associated potential risks to fenceline communities (Ref. 15), and, following peer review, EPA has been applying these approaches in subsequent risk evaluations (*e.g.*, Draft Risk Evaluation for Tris(2-chloroethyl) Phosphate (TCEP) (Ref. 16) and 1,4-dioxane Draft Supplemental Risk Evaluation (Ref. 17)). 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.

After considering the comments, and as described in Unit IV.C., EPA is finalizing the changes to the PESS definition as proposed to better reflect the Agency's commitment to fully consider the impacts a chemical undergoing TSCA risk evaluation may present to communities already experiencing disproportionate and adverse human health or environmental burdens.

5. *Risk-based occupational exposure values.* As part of the proposed rule, EPA solicited comment on how EPA could improve the transparency of any risk-based occupational exposure values derived from the risk evaluation process. Commenters generally expressed a strong desire for more opportunity for public review and scientific input on how risk-based occupational exposure values are derived, and a more formalized approach for the development of any corresponding regulatory limits.

Although occupational exposure values for some of EPA's first 10 chemicals came out at a different time than the risk evaluations themselves, EPA does not intend this to be the practice moving forward. More recently, for example, EPA put out a draft risk-based occupational exposure value in the Draft Risk Evaluation for TCEP (Ref. 16) released for peer review. EPA will continue to do that as a matter of practice. Further, and in response to comments on the proposed rule, EPA is including a commitment in the regulatory text to calculate a risk-based occupational exposure value in the draft risk evaluation where unreasonable risk to workers through inhalation is identified. As part of this commitment, EPA will explain in each risk evaluation how the value was calculated.

To avoid confusion, EPA is no longer referring to the risk-based occupational exposure value calculated in the risk evaluation as an Existing Chemical Exposure Limit (ECEL). The risk-based occupational exposure value calculated in the risk evaluation is based on the most sensitive hazard endpoint and standard occupational exposure scenarios assumption (*i.e.*, 8 hours a day, 5 days a week, 250 days a year, for 40 years), and by law, cannot consider costs or other non-risk factors. The value is not a regulatory limit or level, though it can be used to inform risk management. The value is only relevant to workers in occupational settings—not to consumers or the general population. The value also does not take into account any existing occupational exposure controls, though, as described elsewhere in this document, EPA will consider such controls as part of developing regulations required under TSCA section 6(a) to address unreasonable risk.

Considerations for risk management approaches are outside the scope of this rule. However, when proposing any regulatory limit during the risk management phase, EPA may consider costs and other non-risk factors, such as technological feasibility, the availability of alternatives, the continued need for critical or essential uses, the potential for different occupational requirements for these uses, and existing occupational exposure control approaches and technologies. As such, any regulatory occupational existing chemical exposure limit or ECEL for risk management purposes could differ from the occupational exposure value calculated in the risk evaluation based on additional consideration of exposures and non-risk factors consistent with TSCA section 6(c).

While in many cases EPA won't be aware of all of those non-risk factors until it actively engages in the risk management process for a specific chemical, there are also times when EPA will be able to describe in the risk evaluation circumstances that may lead any regulatory limit to differ from the calculated occupational exposure value. In the Draft Risk Evaluation for Formaldehyde (Ref. 18), for example, EPA was able to state with certainty that any ECEL developed for occupational safety risk management purposes would be certain to differ from the calculated exposure value included in the draft Risk Evaluation. In that instance, EPA was able to recognize unique challenges

associated with the formaldehyde draft risk evaluation, including indistinguishable sources of exposure and a calculated occupational exposure value that fell below the 50th to 95th percentile of measured concentrations in residential indoor air. Where such information is available, EPA would expect to provide similar clarity on this point in future risk evaluations.

EPA has valued the engagement with industry and other Federal agency stakeholders on some of EPA's proposed risk management measures to date, and the Agency is committed to making adjustments as appropriate to ensure any occupational regulatory restrictions are both protective and implementable. As described in Unit IV.F.1., 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, 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. 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.

G. Scientific Guidance and Procedures

1. *In general.* 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)). EPA codified the use of appropriate Agency guidance (which can also include Agency guidelines, frameworks, handbooks, or standard operating procedures) in the development of risk evaluations in the 2017 final rule and proposed to maintain that regulatory text in the proposed rule (40 CFR 702.37(a)(1)). EPA received support from public commenters on this provision and is finalizing it as proposed. TSCA risk evaluations require the Agency to conduct hazard, exposure, and fate assessments, quantify both acute and chronic effects, as well as assess the risks to the environment. The breadth of risk evaluations requires a breadth of expertise and methods, processes, protocol, and models. Agency guidance and methodology documents have and will continue to provide process and method transparency to Agency scientific work products. EPA will use the appropriate guidance based on the application of methods, approaches, and science policy decisions used in TSCA risk evaluations. EPA will continue to use existing Agency guidances in the development of TSCA risk evaluations. EPA may develop and use additional guidance as needed using a transparent process. Additionally, the TSCA program will work closely with other EPA offices to ensure the use of the best available science, specifically where another office may have expertise specific to a certain chemistry or method employed in a risk evaluation.

2. *Peer review.* Science is the foundation that supports the work of EPA. The use of best available science is vital to the credibility of the Agency's determination of whether a chemical presents an unreasonable risk, decisions on how best to manage that risk, the Agency's effectiveness in pursuing its mission to protect human health and the environment, and the public's trust in Agency decisions. Peer review, as recognized by TSCA section 26(h), is an integral consideration in ensuring Agency decisions are consistent with the best available science. Peer review can ensure the use of reasonably available information to make decisions is based on the weight of scientific evidence. Conducting transparent and independent scientific peer review, along with providing opportunities for public comment, has been and will remain an important component of the TSCA risk evaluation process. Peer reviews on TSCA risk evaluations to date have proven extremely instructive and resulted in more robust and scientifically defensible products and improvements to EPA methods used in the risk evaluation process.

The 2017 final rule codified peer review as a component of the risk evaluation process. In the proposed rule, EPA included amendments to the regulatory text on peer review attempting to clarify the Agency's flexibility in determining how and what to peer review. The proposed regulatory text read: "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)." EPA received many comments on the proposed changes to this regulatory provision, most of which were unsupportive. Many expressed concern that the flexibility sought in this change may result in limited and less transparent peer reviews, counter to the scientific standards required by the statute. Specifically, commenters found that use of the phrase "expected" to conduct peer review left open the possibility that EPA could forgo peer review altogether. Commenters also expressed concern about a piecemeal approach that may result if the Agency only peer reviewed "portions" of future risk evaluations, which commenters noted could result in portions of a risk evaluation not undergoing peer review, or that EPA may shield from peer review particular lines of evidence used in making a determination of unreasonable risk.

The Agency fully intends to act consistently with the EPA Peer Review Policy Statement, which states in part, "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 . . ." (Ref. 19). In the final rule EPA has amended the proposed regulatory text to affirm that EPA will conduct peer review: "EPA *will* conduct peer review activities on risk evaluations . . ." (40 CFR 702.41). EPA agrees with commentors that peer review is necessary and integral to robust TSCA risk evaluations, and the Agency fully intends to continue to conduct peer review on TSCA risk evaluations consistent with longstanding Agency and OMB guidance.

With respect to EPA's use of "or portions thereof" of in the proposed rule regulatory text, EPA did not intend that phrase to reflect a policy change, but rather a clarification of the allowable scope of peer review under both the EPA Peer Review Handbook 4th Edition 2015 (EPA Handbook) (Ref. 20) and OMB's Information Quality Bulletin for Peer Review (Peer Review Bulletin) (Ref. 21). As a general matter, EPA believes that peer reviewing all or most of the risk evaluation will likely be standard practice for the foreseeable future. EPA notes that, under the Peer Review Bulletin, Agencies also have "broad

discretion in determining what type of peer review is appropriate." The Peer Review Bulletin instructs agencies "to consider tradeoffs between depth of peer review and timeliness". This includes the consideration of costs of peer review—both direct costs and costs of potential delay in government and private actions that result from peer review, including delays in risk management actions to address unreasonable risks.

After consideration of comments, EPA has removed the "or portions thereof" language in the regulatory text, as this in an unnecessary codification of a practice that is already allowed under existing guidance documents. The final rule makes clear that EPA will conduct peer review activities on TSCA risk evaluations, and expects those activities and related decisions regarding the appropriate scope and type of peer review to be consistent with the applicable guidances from OMB and EPA.

EPA expects that, at some point in the future, risk evaluations may use previously peer reviewed scientific approaches, models, and/or methods for similar chemicals or exposure scenarios. In those cases, peer review can focus on the novel information, applications, and analysis that will benefit from independent, expert peer review. For some risk evaluations, it may be more appropriate to peer review solely the weight of evidence determination. The intent of the proposed provision was to ensure Agency discretion and flexibility when determining the approach to and scope of peer review. Both the Peer Review Bulletin and the EPA Handbook clearly outline circumstances where additional peer review may not be necessary. An example would include work that has been previously peer reviewed in a manner consistent with the Peer Review Bulletin and the EPA Handbook. For each risk evaluation, EPA will consider the complexity, novelty, and any prior peer review to determine the appropriate approach to and scope of peer review to apply.

Additionally, and as discussed in the proposed rule, EPA also expects that a TSCA risk evaluation may use peer reviewed products (*e.g.*, risk assessments, hazard assessments, models), or portions thereof, developed by another EPA office or other authoritative body (*e.g.*, state, national, or international programs). EPA will use existing assessments and review scientific information in a transparent manner, including documenting how the information used represents the best available science, is fit-for-purpose, and supports the weight of evidence.

Some commenters question EPA's position of not seeking peer review on the unreasonable risk determination. Consistent with the 2017 final rule, 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 evaluation, not a review 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)).

EPA received a number of comments on the type of peer review that may be employed for TSCA risk evaluations. Consistent with the 2017 final rule, EPA has not codified the type of peer review or specific reviewers. The Peer Review Bulletin recognizes that "different types of peer review are appropriate for different types of information." The Peer Review Bulletin grants Agencies discretion in determining what type of peer review is appropriate. Agencies are directed to choose a peer review mechanism that is adequate, "[considering] the novelty and complexity of the science to be reviewed, the relevance of the information to decision-making, the extent of prior peer reviews, and the expected benefits and costs of additional review". The level of rigor of the peer review should be based on whether the information contains methods or models that are precedent-setting, presents conclusions that are likely to change prevailing practices, or will likely affect policy decisions that have a significant impact.

EPA retains the discretion to employ various types of peer review, including panel or letter reviews. EPA expects to use letter reviews as appropriate, but anticipates that letter reviews will be the exception while panel reviews will be preferred. EPA will continue to use on a case-by-case basis the Science Advisory Committee on Chemicals (SACC) (the advisory committee required by TSCA section 26(o)) to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues relating to the implementation of TSCA.

Finally, EPA proposed removing the reference to specific versions of guidance documents. The Agency recognizes that guidance may be updated and/or names modified and, to avoid confusion as to which guidance documents will be used, the Agency proposed 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." A number of commenters expressed concern at the ambiguity and lack of clarity that could arise for both EPA staff and stakeholders without specific documents named. For the final rule, EPA determined not to codify specific titles and has retained the proposed language with minor adjustments for additional clarity. Codifying specific documents into regulatory text is problematic if and when documents are updated or are supplanted by a new version. Although not named in the regulatory text, EPA peer review activities for TSCA risk evaluations will generally by guided by EPA Peer Review Handbook 4th Edition 2015 (Ref. 20) and OMB's Information Quality Bulletin for Peer Review (Ref. 21), successor versions of these documents, and/or any requirements that may later supplant these documents.

H. Scientific Standards

TSCA section 26(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." TSCA 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.

As described in Unit IV.C., EPA proposed to eliminate both definitions from the regulatory text. Aside from being unnecessary, EPA believes codifying definitions for these scientific terms limits the Agency's ability to adapt to the changing science of risk evaluation, as well as the science that informs risk evaluation, and limits the Agency's flexibility to implement and

advance novel science. Additional discussion on how EPA intends to uphold TSCA's scientific standards for "best available science" and "weight of scientific evidence," as well as EPA's expected application of systematic review methods for identifying and assessing reasonably available information, is provided in the sections that follow.

1. *Best available science.* As described in the 2017 final rule, EPA continues to believe that the "best available science" is science that is reliable and unbiased. Use of best available science involves 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). Additionally, as required in TSCA section 26(h), in determining the "best available science," EPA must consider as applicable:

2.

(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.

EPA's implementation of the "best available science" standard in TSCA is further informed by longstanding EPA and OMB guidance. The OMB Information Quality 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. 22), 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. 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 advancing and that risk information may need to be updated over time."

As described in Unit IV.C., the Agency does not believe codifying a definition of "best available science" provides any additional transparency or improves consistency, as EPA must for each risk evaluation determine what is the best available science based on the reasonably available information. EPA is furthering its commitment to transparency by finalizing the proposed regulatory text requiring EPA to "document that the TSCA risk evaluation is consistent with the best available science and based on the weight of the scientific evidence" in 40 CFR 702.37(a). With respect to "best available science," EPA is also finalizing the list of considerations for determining what constitutes the best available science—considerations that are taken directly from TSCA section 26(h). In response to some commenters' concerns that the prefacing language (*i.e.*, "shall include, but are not limited to, . . .") did not match with section 26(h)—and could imply an intention by EPA to ignore the statutory considerations or opaquely apply different ones—EPA is adjusting that language in the final rule to state, as the law states, that EPA "shall consider as applicable . . .".

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 federal, state or international authoritative bodies. EPA may consider whether these existing assessments or reviews represent the best available science as required under TSCA and use portions of them to directly inform a risk evaluation. Additionally, where appropriate and consistent with the White House's *Guidance for Federal Departments and Agencies on Indigenous Knowledge,* EPA will consider including and applying Indigenous Knowledge to inform decisions related to the best available science (Ref. 23).

As stated in 40 CFR 702.37(a)(1), the Agency will use appropriate Agency guidance in the development of the TSCA risk evaluations under this rule. TSCA section 26(l) provides further support for this approach, requiring 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. This approach is also consistent with the approach taken in other EPA programs (*e.g.*, Office of Water's implementation of the Clean Water Act and the Office of Air and Radiation's implementation of the Clean Air Act), none of which codify a definition of "best available science."

2. *Systematic review and fit-for-purpose approaches.* As described in Unit IV.C., EPA is, as proposed, eliminating the codified definition of "weight of scientific evidence" in the final rule, which EPA believes inappropriately conflated the concepts of "weight of scientific evidence" with "systematic review." Many commenters supported this approach and further support the requirement that EPA codify the use of systematic review, but recommended further clarification as to how EPA will incorporate systematic review into the process for conducting TSCA risk evaluations.

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 comprehensively through unbiased, transparent and objective data collection and data evaluation, using methods consistent with the general principles of systematic review. EPA believes that integrating appropriate and applicable systematic review methods into the TSCA risk evaluations is critical to meeting the scientific standards as described in TSCA section 26(h) and (i). Systematic review methods may include a systematic review, such as that described in the *Draft TSCA Systematic*

Review Protocol Supporting TSCA Risk Evaluations for Chemical Substances: A Generic TSCA Systematic Review Protocol with Chemical-Specific Methodologies (Ref. 24) or the EPA's *Office of Research and Development Staff Handbook for Developing IRIS Assessments* (Ref. 25), or may be an approach that incorporates the principles of systematic review. The principles of systematic review are well-established and include "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. 26). EPA has finalized the requirement to use and document systematic review methods to assess reasonably available information, and included flexibility to consider the appropriate level of review for a given evidence stream, while still ensuring EPA meets the requirements of TSCA sections 26(h) and (i) (see § 702.37(b)(2)).

The flexibility to apply appropriate and relevant systematic review methods is necessary in the development of TSCA risk evaluations. The National Academies of Science Engineering and Medicine (NASEM) report (Ref. 27), in their review of the *Application of Systematic Review in TSCA Risk Evaluations* (Ref. 28), highlights this need for alternative approaches, stating that "under some circumstances there may be reasonable alternatives to carrying out a de novo systematic review; for example, the relevant literature may be non-existent or too limited in scope or there may be a recent systematic review that meets quality standards. In some cases, it may be possible to use an alternative approach to systematic review as long as it meets the transparency, consistency, reproducibility, and comprehensiveness requirements of evidence-based methodologies." EPA expects that future risk evaluations may use, for example, an existing hazard assessment conducted by an authoritative source, in lieu of conducting a de novo assessment. EPA would review this assessment in a transparent, unbiased and objective way, which may require supplementing the assessment with more recent literature or reviewing the weight of evidence, but may not repeat systematic review on all supporting information. In alignment with the recommendations from the NASEM report, when EPA uses an alternative methodology, it will document why it has done so in lieu of the more traditional systematic review.

Traditional systematic review includes performing—as described and documented in a defined protocol that can be applied across multiple lines of evidence—a literature search and screening to identify relevant information, followed by data quality evaluation (addressing factors such as relevancy and bias), data extraction, and evidence integration. The TSCA program recognizes that the science of systematic review continues to evolve, and will continue to develop its systematic review methods of data collection, data evaluation, evidence synthesis and integration, while partnering with other EPA Offices to advance and implement tools, methods, and efficiencies to systematically collect and evaluate literature. The procedures required for ensuring objectivity, transparency and limiting bias to extent possible in the collection and review of data for TSCA risk evaluations must be flexible enough to account for the variety of hazard and exposure information available to inform TSCA risk evaluations, and also be implementable within the statutory deadlines. EPA has and will continue to implement chemical specific approaches, including the development of chemical-specific protocols that are flexible, timely, and relevant for the types, quality, and quantity of information available and needed in a risk evaluation. EPA will apply and document the systemic review methods of data collection, evaluation, and integration that are commensurate with the relevant complexity of the assessment and nature of the information available, and carried out in a transparent manner that permits completion of risk evaluations within the timeframes that Congress provided.

3. *Weight of scientific evidence.* As described in Unit IV.C., EPA is, as proposed, eliminating the codified definition of "weight of scientific evidence"—instead relying on long-established Agency guidance documents to guide weight of scientific evidence analyses under TSCA.

There are certain principles of WOSE that are universal, including foundational considerations such as objectivity, transparency and consideration of the strengths and weaknesses of lines of evidence. The phrase WoSE or weight of evidence (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 guidance used to classify carcinogens (Ref. 29). 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. 30). EPA agrees with this assessment, and, as such, concluded that an alternative codified definition would not provide additional transparency or certainty to the required use of WoSE in TSCA risk evaluations. However, as described in Unit IV.H.1., this rule codifies a commitment to transparency by finalizing the proposed regulatory text requiring EPA to "document that the TSCA risk evaluation is consistent with the best available science and based on the weight of the scientific evidence" in 40 CFR 702.37(a).

To meet the law's requirement to base decisions in TSCA risk evaluations on the "weight of the scientific evidence," EPA expects to rely on established Agency guidance documents. These peer reviewed guidances provide consistency and formality to a process that looks to integrate multiple and often heterogenic lines of evidence. At this time, EPA will primarily look to four documents for implementing WoSE in TSCA risk evaluations: *Weight of Evidence in Ecological Assessment* (Ref. 31), *Guidelines for Carcinogen Risk Assessment* (Ref. 29), *Endocrine Disruptor Screening Program Weight-of-Evidence: Evaluating Results of EDSP Tier 1 Screening to Identify the Need for Tier 2 Testing* (Ref. 32), and *ORD Staff Handbook for Developing IRIS Assessments* (Ref. 25). EPA recognizes that there are other international approaches that may also be applicable and will transparently document their use. 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 when drawing conclusions. The results from the scientifically relevant published or publicly available studies in the peer reviewed scientific journals, studies conducted in accordance with Organization for Economic Cooperation

and Development (OECD) or EPA guidelines, gray literature, and/or any other studies, scientific information, or lines of evidence that are of sufficient quality, relevance, 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. EPA will provide a summary WoSE narrative or characterization to accompany a detailed analysis to transparently describe the conclusion(s), as well as explain the selection of the studies or effects used as the main lines of evidence and relevant basis for conclusions.

I. Process for EPA Revisions to Scope or Risk Evaluation Documents

As part of the proposed rule, EPA added 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 did not provide any such criteria or procedures. As described in the proposed rule, EPA reasoned that these new procedures and criteria would provide greater certainty and transparency for stakeholders, and would enable EPA to make forward progress on prioritizing, reviewing and managing existing chemicals as Congress intended, without diverting limited resources towards continuously revisiting final risk evaluations.

With respect to final scope documents, EPA proposed 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. The proposed rule further contemplated 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. EPA received no public comments on these changes and is finalizing as proposed.

With respect to draft risk evaluations, EPA proposed to reflect and describe any changes to the draft document in the final risk evaluation rather than reissue the risk evaluation in a second draft form. EPA noted that, 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. Further, this ensures that feedback is appropriately considered and reflected without unduly delaying progress towards completion of the risk evaluation.

A few commenters objected to this aspect of the new procedures, and argued that EPA must share significant changes to draft risk evaluations prior to finalization under the Administrative Procedures Act (APA) (5 U.S.C. 551 *et seq.*). EPA shares commenters' perspective regarding the need for transparency during the risk evaluation process, and the importance of considering stakeholder feedback. In light of the improvements EPA is finalizing in this procedural rule, EPA does not anticipate many significant changes between draft and final risk evaluations moving forward. However, where there are significant changes, the rule provides EPA with flexibility to seek additional public comment or independent review of those changes prior to finalizing. With respect to the comment about the APA, TSCA risk evaluations are scientific work products—not regulatory actions—and fall outside the scope of APA requirements related to proposed and final rulemaking. As such, EPA is finalizing this provision as proposed.

With respect to revision of final risk evaluations, EPA also proposed a general practice 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. As noted in the proposed rule, 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.

EPA proposed to make exceptions to that general practice where revisions to a final risk evaluation outside of re-prioritization of a chemical are in the interest of protecting human health or the environment. For example, the exception might be warranted in the event a scientific error 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 rule, including publication of a new draft and final risk evaluation, solicitation of public comment, and, as appropriate, peer review.

Commenters were generally supportive of this change, noting its potential to provide greater efficiency and increased pace of chemical review. One commenter noted that regulatory text had a potentially inadvertent mistake in describing the exception, referring to human health *and* the environment, instead of human health *or* the environment (see 40 CFR 702.43(g) as proposed—". . . except where EPA has determined it to be in the interest of protecting human health and the environment to do so . . ."). EPA agrees with commenter and did not intend to limit application of the exception to instances where there is both a human health and environmental interest. As such, EPA is replacing the "and" with an "or" in the final rule, but is otherwise finalizing these provisions as proposed.

J. Process and Requirements for Manufacturer-Requested Risk Evaluations

EPA proposed a number of changes to the process and requirements for manufacturer- requested risk evaluations (MRREs). TSCA section 6(b)(4)(C)(ii) allows a chemical manufacturer to request that the Agency conduct a risk evaluation of a chemical substance that they manufacture. Consistent with TSCA section 6(b)(4)(C)(ii), EPA established the "form . . . manner and . . . criteria" for such requests in the 2017 final rule. Based on experience in implementing that process to date, EPA believes the proposed modifications are necessary to increase clarity and expectations, and to better position the Agency to grant and carry out MRREs moving forward.

As described in the proposed rule, the current process for MRREs is unrealistic and unsustainable. Amongst other things, the current process allows MRRE requesters to provide EPA with a narrow set of information relevant to only certain conditions of use; requires EPA to quickly grant or deny the request, and then starts the clock for EPA to complete an entire risk evaluation on the chemical substance with the three-year statutory deadline. The proposed changes would require that more fulsome information be included in incoming requests, allow EPA additional time to properly review requests and determine any additional information needs prior to initiating the evaluation, and provide flexibility in the process to accommodate additional data collection or development during the risk evaluation.

EPA received a number of comments on the proposed changes ranging from general support to general opposition. Some commenters provided suggestions for further clarifying requirements, improving the contemplated processes, and increasing overall transparency. Other commenters shared concerns that, on the whole, the changes would make MRREs unattractive to those who might otherwise consider submitting requests. EPA describes these comments further in this section, as well as in the Agency's Response to Comments document (Ref. 6). After consideration of the comments, EPA is finalizing much of the regulatory text at 40 CFR 702.45 as proposed, notwithstanding the changes described in this section. EPA would refer the public to the preamble to the proposed rule for a more fulsome discussion of each of the substantive provisions, and EPA's expected implementation (Ref. 5).

1. *Scope of request.* The 2017 final rule allowed manufacturers to request a risk evaluation on particular conditions of use of interest to the requesting manufacturer, leaving the Agency with the heavy burden of identifying the remaining conditions of use for the chemical substance. For some, this provision created the misperception that, in instances where the requesting manufacturer only identifies a narrow set of circumstances, EPA would or could carry out a similar, narrowly-scoped risk evaluation. Such an action would unequivocally contravene EPA's statutory authority. In the proposed rule, EPA adjusted this language so that manufacturers are only permitted under the law to make requests for evaluations of a chemical substance—not individual conditions of use or subsets of conditions of use—consistent with the statutory language in TSCA section 6(b)(4)(C) (stating that EPA "shall conduct and publish risk evaluations . . . on a chemical substance . . ."). This aspect of the proposed rule generated a range of comments. Several commenters supported the clarification and agreed that conducting use-based MRREs was beyond EPA's statutory authority. Others objected to the change as setting too broad a scope that would eliminate incentive for submitting MRREs, and frustrate Congress' intent in establishing this process as a "facilitator in interstate commerce."

EPA would emphasize that the proposed rule does not expand the scope of MRREs. In the 2017 final rule, EPA noted that "Although manufacturers may request that EPA conduct a risk evaluation based on a subset of the conditions of use, EPA intends to conduct the risk evaluation in the same manner as any other risk evaluation conducted under section 6(b)(4)(A) . . . . As such, EPA intends to conduct a full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that EPA identifies, just as EPA would if EPA had determined the chemical to be high priority." (Ref. 1). TSCA requires EPA to conduct risk evaluations—including MRREs—on a chemical substance under the conditions of use—not on an individual use or a subset of a chemical's conditions of use. TSCA section 6(b)(4)(E)(ii) also mandates that EPA "shall not expedite or otherwise provide special treatment" to MRREs. Based on public comments regarding the scope of MRREs, it is abundantly clear that this important clarification to the regulatory text is necessary to ensure no future misunderstandings about the required scope of MRREs.

As part of this rule and as discussed in the next section, EPA proposed to require MRRE submitters to provide a more holistic set of information on the chemical as part of the request to better position EPA to grant and successfully undertake MRREs. While EPA acknowledges that it is possible that the additional information requirements may dissuade some manufacturers from submitting these requests, EPA disagrees that the rule would eliminate all incentive. The primary benefit afforded to MRRE requesters is the opportunity to advance a chemical of their choosing ahead of other chemicals that EPA might prioritize, so long as they provide EPA with the requisite information and fees. Additionally, MRRE-driven TSCA section 6(a) final rules or section 6(i)(1) determinations will trigger preemption of state laws and regulations. Nothing in this rule would impact the preemptive effect of an MRRE action (and any associated risk management action) to help reconcile discrepant state-level regulations and facilitate interstate commerce.

Finally, EPA disagrees with commenters that suggest EPA is further disincentivizing MRREs with the single risk determination approach on the chemical substance. Again, the risk determination approach does not mean EPA will, in every instance, find that a chemical substance presents unreasonable risk. While perhaps MRRE requesters would prefer that EPA determine that the condition(s) of use of interest of their chemical does not present unreasonable risk, such an outcome is not their prerogative. Further, EPA does not believe the possibility of an unreasonable risk determination should be a deterrent to future MRRE requesters. At the end of regulatory process, when EPA has eliminated any identified unreasonable risks pursuant to TSCA section 6(a), the manufacturer gets regulatory certainty. And the public can have confidence that the chemical can be safely used in commerce.

2. *Contents of request.* EPA also proposed some specific updates to the required contents of a MRRE, and the criteria upon which EPA will judge completeness and sufficiency. A manufacturer requesting that EPA conduct a risk evaluation 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 TSCA section 2, 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). With 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)). As described in the proposed rule, EPA believes that the 2017 final rule inappropriately shifted much of the information gathering burden for MRREs to the Agency.

Amongst other criteria, EPA proposed to require that MRRE requests 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 requesting manufacturer's interests. These changes would require more fulsome information come in as part of the request, enabling a more effective process for reviewing the request, and making it more likely that EPA will ultimately be able to grant and undertake the evaluation within the statutory timeline provided.

A number of commenters supported these changes, and expressed agreement with EPA's reasoning and proposed approach. Several commenters offered suggestions for including more specificity in the requirements for MRRE contents at 40 CFR 702.45(c). In response to these comments, EPA is making a number of adjustments to the regulatory text in the final rule.

First, EPA agrees with adding more clarity on how manufacturers should determine the "known or reasonably ascertainable" information that must be included in the request. As described in the preamble to the proposed rule, 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 40 CFR 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. In response to comments on the proposed rule, EPA is codifying certain additional aspects of this discussion on the due diligence standard in regulatory text in the final rule to further underscore and clarify expectations for information to be submitted as part of an MRRE. Specifically, EPA is modifying 40 CFR 702.45(a) to describe the level of effort that should be undertaken to gather information that is "known to or reasonably ascertainable by" the requesting manufacturer. Relatedly, EPA is clarifying in the regulatory text that, in the event that a group of manufacturers submits a MRRE, the information requirements in paragraphs (a), (c) and (i) would apply to all manufacturers—not just the primary contact submitting the request. Second, at the suggestion of several commenters, EPA is striking the regulatory text in the final rule regarding identification of potentially exposed or susceptible subpopulations that the manufacturer believes to be relevant. As noted by commenters, EPA must ultimately identify PESS—not the requesting manufacturer. Elimination of this requirement would lessen burden on requesters and avoid confusion that a requester's judgment on this issue could supplant that of EPA. Third, EPA agrees with commenter that an additional requirement of identifying the known locations where the chemical is used, and the consumer products (if any) containing the chemical would be helpful to EPA in ensuring consideration of all exposures and conditions of use. While EPA believes submission of this information already falls within the umbrella of 40 CFR 702.45(c)(5), EPA sees value in explicitly describing this in the regulatory text as the commenter suggests, and is adjusting the final rule accordingly.

EPA also appreciates the concern shared by some commenters that ambiguity in the information/content requirements may create uncertainty for manufacturers weighing whether or not to submit a request, particularly in light of the commitment MRRE requesters make to provide EPA with information necessary to carry out the risk evaluation and the associated fee requirements for MRREs. While EPA believes the changes described in the proposed rule and the additional ones contemplated for the final rule do bring additional clarity, EPA welcomes and encourages pre-submission consultations to discuss information needs further. Moreover, the additional processes EPA is contemplating in this rule for MRREs should help bring greater clarity to information needs much *earlier* in the process—either before EPA has granted request, or prior to EPA having undertaken significant amounts of work—and therefore before significant expenses have been incurred under the fee schedule. Lastly, EPA developed a guidance document in 2017 to assist interested persons in developing draft risk evaluations for submittal to EPA (Ref. 33). While the MRRE process does not require submittal of a draft risk evaluation, the guidance describes the science standards, data quality considerations and other information relevant to EPA's risk evaluation process that may be of use to manufacturers interested in developing an MRRE request. As resources allow, EPA may consider updating this 2017 guidance and further developing particular sections to better assist potential MRRE submitters.

A few commenters disagreed with EPA that the primary burden should be on manufacturers to provide sufficient information for the risk evaluation, and that EPA may be better positioned to gather the necessary information using its various statutory authorities. 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. Still, EPA recognizes that manufacturers may not, after making a reasonable amount of effort, be able to provide the Agency with all the information necessary to complete the risk evaluation. EPA proposed processes for how such shortcomings will be identified and addressed, including opportunities for manufacturers to request EPA exercise its statutory authorities to fill in any gaps. These changes set clearer expectations for what EPA needs to undertake in a risk evaluation, and establishes a process for productive engagement with requesting manufacturers toward meeting those needs.

These amendments also satisfy the Ninth Circuit's remand without vacatur of the relevancy and consistency provisions of the currently codified language at 40 CFR 702.37(b)(4) and (6), which address the information requirements for, and application of the TSCA section 26 scientific standards to, an MRRE (Ref. 7).

3. *EPA process for reviewing requests.* EPA proposed a number of changes to how the Agency will review MRREs in 40 CFR 702.45, including additional measures for transparency and public engagement. EPA would again refer the public to the preamble of the proposed rule for a general description of the procedural steps. At a high level, the process steps can be summarized as

follows: Upon receipt of a MRRE, EPA will provide the public with notice and begin reviewing the request for completeness. Where the MRRE request appears complete, EPA will open a docket for the MRRE and supporting information, and solicit public comment. Following a second review, where EPA believes there is sufficient information, EPA will grant the request, and proceed to publish a draft list of conditions of use and solicit additional comment. Following this comment period, and when EPA believes it has all necessary information, EPA will formally initiate the evaluation and follow all the same processes and requirements for EPA-initiated risk evaluations in subpart B. The proposed rule also included processes to resolve information needs as they might arise during the process, and an opportunity for requesting manufacturers to withdraw their request.

Nearly all commenters expressed support for the new process steps, agreeing with EPA that the process in the 2017 final rule does not allow enough time for adequate review of MRREs. Commenters also agreed that Congress did not intend MRREs to differ from EPA-initiated risk evaluations, that TSCA does not permit increased burdens to be placed on EPA in evaluating MRREs, and shared their support for making the new MRRE process and timeframes more comparable to those that precede EPA-initiated risk evaluations. One commenter questioned EPA's characterization of how it would publicly share supplemental information received from the requesting manufacturer during the process (*i.e.*, that EPA would "endeavor, to the extent possible" to publish such information). EPA agrees with the commenter that this was not confidence-inspiring language. Instead, EPA is committing as part of this final rule to promptly publish in the MRRE docket any supplemental information received from the requesting manufacturer, subject to the Agency's requirements with respect to the protection from disclosure of CBI.

The same commenter also pointed out an inconsistency between the "preference" criteria in TSCA section 6(b)(4)(E)(iii) and the language in the proposed rule. Upon further review, EPA agrees with the commenter that the language in 40 CFR 702.45(j)(2) warrants adjustment and is striking the phrase "in excess of the 25% threshold" in the final rule accordingly, in order to be more consistent with the statutory text on this point. Namely, when reviewing MRRE requests, TSCA requires EPA to give preference to requests for risk evaluations on chemical substances for which restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment. To date, EPA has not had to apply any preference criteria as the number of MRRE requests pending at any given time has been below the 25% threshold.

For clarity and consistency with the TSCA fees provisions in 40 CFR 700.45, EPA has added a parenthetical to the regulatory text about fees in the event of withdrawal. Specifically, the proposed text referred to 40 CFR 700.45(c)(2)(x) or (xi) and EPA has added a parenthetical to recognize that, for subsequent fiscal years, the fees rule already incorporates an inflation adjustment per 40 CFR 700.45(d). EPA is also making minor changes to the regulatory text at 40 CFR 700.45(e)(8) and (9) on unfulfilled information needs and the initiation of the risk evaluation to increase clarity in the process, and at 40 CFR 700.45(k) to correct a typo in the statutory citation.

Aside from the minor adjustments noted in this section, EPA is finalizing the remainder of the regulatory text at 40 CFR 702.45 as proposed.

K. Interagency Collaboration

EPA is also finalizing 40 CFR 702.47 as proposed. 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. EPA continues to collaborate with other relevant Federal agencies and plans to further coordinate with them regarding interagency engagement and collaboration when carrying out the functions and responsibilities assigned to the Agency under TSCA section 6(b), starting even before the initiation of the prioritization process. EPA intends to develop and, subject to the interests of Federal agencies involved, execute Memoranda of Understanding that memorialize these interagency information exchange, review and comment, and collaboration best practices. Such practices would address engagement and collaboration with Federal partners to help ensure EPA has timely access to information to support a comprehensive understanding of, and not limited to, a chemical substance's conditions of use and their importance to national security or critical infrastructure, the hazard and exposure potential of that chemical, and existing safety measures Federal agencies already have in place for their uses.

With respect to critical/essential uses by other Federal agencies, EPA recognizes that identification and documentation of such uses requires substantial and early interagency engagement, as well as safeguards for national security or other sensitive information. Uses of a chemical that may be critical/essential are conditions of use of the chemical and, as such, will be evaluated in risk evaluations. Federal agencies should identify their uses (including those they believe to be critical or essential uses) as early as possible (*e.g.*, during the prioritization and/or risk evaluation processes) to help inform EPA's development of regulations for chemical substances under TSCA section 6(a) to the extent necessary to address unreasonable risk upon completion of relevant risk evaluations. EPA will engage with agencies that identify critical/essential uses to obtain the necessary level of information to support the consideration of those uses in advance of any proposed rule. For each chemical substance, EPA intends to engage at least four times with interested Federal agencies and departments: first, before EPA begins the prioritization process for the substance; second, during the 9-to-12 month prioritization process; third, during the development of the draft risk evaluation; and fourth, after the draft risk evaluation has been released for public comment. At each engagement, in addition to receiving any information about the substance Federal agencies wish to share, EPA would share scientific and other information about its progress on the risk evaluation, including any information it has developed related to Federal agency uses of the substance.

V. Reliance Interests

As described in the proposed rule, EPA considered to what extent stakeholders may have reliance interests in previous statutory interpretations underpinning the 2017 final rule, and concluded that there are either no reliance interests on those past statutory interpretations, or that any such interests are minor (Ref. 5 at p. 74316). 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 the exception of modified procedural requirements for voluntary requests for risk evaluation that are submitted by manufacturers.

A few commenters disagreed with EPA's discussion of reliance interests. They argued, for example, that companies submitted MRREs under the

2017 procedural rule with expectations related to use-specific risk determinations and preemption outcomes. Another argued that all manufacturers who deal with chemicals under review will become subject to capricious regulation in light of the elimination of the "best available science" and the peer review requirements. Another commenter suggested the high likelihood of inconsistency between risk evaluations creates substantial reliance interests.

First, with respect to commenters' arguments regarding preemption, as described previously, EPA believes commenters fundamentally misunderstand the applicability of TSCA section 18(a), and how the preemptive effects of that provision are unaffected by a single chemical risk determination. As noted earlier, permanent preemption is triggered under section 18(a)(1)(B)(ii) if EPA issues first a scope of the risk evaluation under section 6(b)(4)(D) and then a section 6(a) final rule or a section 6(i)(1) determination based on the risk evaluation. These factors are not affected by a single risk determination approach. Further, because the 2017 rule does not mandate use-based risk determinations, EPA disagrees that MRRE submitters, for example, could have demonstrable reliance interests on that particular approach or outcome. Second, with respect to "best available science," nothing in this rule modifies the statutory requirement that EPA apply the best available science in all risk evaluations. Likewise, nothing in this rule would eliminate peer review on future risk evaluations. Third, EPA disagrees that this rule will create a high level of inconsistency between risk evaluations. To the contrary, EPA believes this rule—and the important clarifying changes it would codify—will bring greater consistency to future risk evaluations and more certainty and transparency for the regulated community and public.

EPA further maintains that, 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 this 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 final 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.**

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13. U.S. EPA. EJSCREEN: Environmental Justice Screening and Mapping Tool. *https://www.epa.gov/ejscreen.*
14. U.S. EPA. EnviroAtlas. *https://www.epa.gov/enviroatlas.*
15. 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.*
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VII. 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 is available in the docket. EPA prepared an analysis of the potential costs associated with this action. This analysis, which is in the docket, is summarized in Unit VII.B.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared to replace an existing approved ICR has been assigned EPA ICR No. 2781.02 and is identified by OMB Control No. 2070–0231. You can find a copy of the new ICR document (Ref. 4) in the docket for this rule, 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 rule replacement ICR addresses the information collection requirements contained in the current regulations as well as in the amendments identified in this final rule. As addressed in the currently approved ICR and pursuant 40 CFR 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 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 amendments to information requirements for manufacturer-requested risk evaluations, including 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 IV.J. for additional information about these 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 associated with the amended requirements 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: 1 annually.

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. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

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 manufacturer-requested risk revaluation 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 rule. 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 of $100 million or more 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 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 addresses 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 does not directly affect the level of protection provided to human health or the environment, EPA expects that this rule will 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 action does not involve technical standards under NTTAA section 12(d), 15 U.S.C. 272.

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 12898 (59 FR 7629, February 16, 1994) and Executive Order 14096 (88 FR 25251, April 26, 2023). This action amends 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 will assist EPA and others (including the public) in understanding, and will assist EPA in determining the potential exposures, hazards and risks to the public, including for overburdened communities associated with existing chemicals as part of a TSCA risk evaluation. The inclusion of overburdened communities among the PESS considered in a chemical risk evaluation will 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 to all potentially affected people, 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 IV.F.4.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action does not meet the criteria set forth in 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 702

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

Dated: April 26, 2024.

Michal Freedhoff,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended to read 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.

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 June 3, 2024. 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 (TSCA), 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.* Pursuant to 15 U.S.C. 2605(b)(4)(E)(i) and in accordance with § 702.45(j)(1), EPA will ensure that the number of chemical substances for which a manufacturer-requested risk evaluation is initiated pursuant to § 702.45(e)(9) is not less than 25% and not more than 50% of the number of chemical substances for which a risk evaluation was initiated upon designation as a High-Priority Substance under subpart A.

(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. In determining best available science, EPA shall consider 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 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 methods to assess reasonably available information, as needed to carry out risk evaluations that meet the requirements in TSCA section 26(h) and (i), in a manner that is 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, industry practices with respect to occupational exposure control measures, 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; and

(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.

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

§ 702.41 Peer review.

EPA will conduct peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A). EPA expects such activities, including decisions regarding the appropriate scope and type of peer review, to be consistent with the applicable peer review policies, procedures, and methods in guidance promulgated by the Office of Management and Budget and 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 or 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(s) 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(s) 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.

(8) For purposes of this section, information that is "known to or reasonably ascertainable by" the requesting manufacturer(s) would include all information in the requesting manufacturer's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know. Meeting this standard requires an exercise and documentation of due diligence that may vary depending on the circumstances and parties involved. At a minimum, due diligence requires:

(i) A thorough search and collection of publicly available information;

(ii) A reasonable inquiry within the requesting manufacturer's entire organization; and

(iii) A reasonably inquiry outside of the requesting manufacturer's organization, including inquiries to upstream suppliers; downstream users; and employees or other agents of the manufacturer, including persons involved in research and development, import or production, or marketing.

(9) In the event that a group of manufacturers of a chemical substance submit a request for risk evaluation under this section, the term "requesting manufacturer" in paragraphs (a), (c), and (i) of this section shall apply to all manufacturers in the group. EPA will otherwise coordinate with the primary contact named in the request for purposes of communication, payment of fees, and other actions as needed.

(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, 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(s) 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) Industrial and commercial locations where the chemical is used or stored;

(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) Consumer products containing the chemical;

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

(ix) 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 from the requesting manufacturer(s) 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 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 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 may:

(i) *Provide the necessary information.* EPA will set a reasonable amount of time, as determined by EPA, for the requesting manufacturer 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 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 that are not fulfilled, because the requesting manufacturer is unable or unwilling to fulfill those needs in a timely manner, the requesting manufacture has produced information that is insufficient as determined by EPA, or 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 identified and received 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, the requesting manufacturer 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.* The requesting manufacturer 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. The requesting manufacturer 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 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 requesting manufacturer(s). At any point prior to the completion of a manufacturer-requested risk evaluation pursuant to this section, the requesting 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 when the requesting manufacturer(s) obtain 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 evaluations 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, 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. 2625(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) (as adjusted by 40 CFR 700.45(d) when applicable), 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 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;

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

(h) Where unreasonable risk to workers is identified via inhalation, EPA's calculation of a risk-based occupational exposure value.

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