E 6560-50-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2025-0260; FRL-8529.1-01-OCSPP]

RIN 2070-AL27

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The U.S. Environmental Protection Agency (EPA, "the Agency") is proposing to amend the procedural framework rule for conducting existing chemical risk evaluations under the Toxic Substances Control Act (TSCA). When conducting an existing chemical risk evaluation under TSCA, EPA must 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 a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation, under the conditions of use. In this action, EPA proposes to rescind or revise certain 2024 amendments to the procedural framework rule to effectuate the best reading of the statute and ensure that the procedural framework rule does not impede the timely completion of risk evaluations or impair the effective and efficient protection of health and the environment.

DATES: Comments must be received on or before **[INSERT DATE 45 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]**. Under the Paperwork Reduction Act, comments on the information collection provisions are best assured of consideration if the Office of Management and Budget (OMB) receives a copy of your comments on or before **[INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].**

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2025-0260, through the Federal eRulemaking Portal at *https://www.regulations.gov*.

Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Kelly Summers, Existing Chemicals Risk Management Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-2201; email address: *TSCA_Framework_Rule@epa.gov.*

For general information contact: The TSCA Assistance Information Service Hotline, Goodwill of the Finger Lakes, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (800) 471-7127 or (202) 554-1404; email address: *TSCA-Hotline@epa.gov*.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. *Does this action apply to me?*

EPA is proposing to amend procedural requirements that apply to the Agency's activities in conducting risk evaluations under TSCA section 6(b) (15 U.S.C. 2605(b)). As part of this action, EPA is proposing certain amendments to the process and requirements that manufacturers (including importers) would be required to follow when requesting that the Agency conduct a 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 proposed

action would apply to them. Potentially affected entities may include:

• Petroleum Refineries (NAICS code 324110);

• Chemical Manufacturing (NAICS code 325);

• Unlaminated Plastics Film and Sheet (except Packaging) Manufacturing (NAICS code 326113);

• Unlaminated Plastics Profile Shape Manufacturing (NAICS code 326121);

• Plastics Pipe and Pipe Fitting Manufacturing (NAICS code 326122);

• Laminated Plastics Plate, Sheet (except Packaging), and Shape Manufacturing (NAICS code 326130);

• Polystyrene Foam Product Manufacturing (NAICS code 326140);

• Urethane and Other Foam Product (except Polystyrene) Manufacturing (NAICS code 326150);

• Plastics Bottle Manufacturing (NAICS code 326160);

• Plastics Plumbing Fixture Manufacturing (NAICS code 326191);

• All Other Plastics Product Manufacturing (NAICS code 326199);

• Tire Manufacturing (except Retreading) (NAICS code 326211);

• Tire Retreading (NAICS code 326212);

• Rubber and Plastics Hoses and Belting Manufacturing (NAICS code 326220);

• Rubber Product Manufacturing for Mechanical Use (NAICS code 326291);

• All Other Rubber Product Manufacturing (NAICS code 326299);

• Pottery, Ceramics, and Plumbing Fixture Manufacturing (NAICS code 327110);

• Clay Building Material and Refractories Manufacturing (NAICS code 327120);

• Flat Glass Manufacturing (NAICS code 327211);

• Other Pressed and Blown Glass and Glassware Manufacturing (NAICS code 327212);

• Glass Container Manufacturing (NAICS code 327213);

• Glass Product Manufacturing Made of Purchased Glass (NAICS code 327215);

• Cement Manufacturing (NAICS code 327310);

• Ready Mix Concrete Manufacturing (NAICS code 327320);

• Concrete Block and Brick Manufacturing (NAICS code 327331);

• Concrete Pipe Manufacturing (NAICS code 327332); and

• Other Concrete Product Manufacturing (NAICS code 327390).

If you have any questions regarding the applicability of this proposed action to a particular entity, consult the technical information contact listed under **FOR FURTHER INFORMATION CONTACT**.

B. *What is the Agency's authority for this proposed action?*

The statutory authority for this proposed action is TSCA section 6(b)(4)(B), which requires EPA to establish, by rule, a process to conduct risk evaluations that meet applicable statutory requirements (15 U.S.C. 2605(b)(4)(B)). As detailed in Units II.A and II.B of this preamble, EPA originally promulgated the procedural framework rule for risk evaluations under TSCA section 6(b)(4)(B) in 2017 and subsequently revised the procedural framework rule in 2024. Unless provided otherwise by law, agencies may reconsider, revise, or rescind prior rules by acknowledging the change, offering a reasonable basis for the change, and taking any significant reliance interests into account. *See FDA v. Wages & White Lion Invs., L.L.C.*, 145 S. Ct. 898, 917 (2025); *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009); *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983). For the reasons set out in Units II and III of this preamble, EPA is proposing to rescind or revise many of the changes made through the 2024 amendments to effectuate the best reading of the statute and address serious concerns arising from Agency and stakeholder experience in application of the amended procedural framework rule. EPA is not currently aware of any significant reliance interests in the 2024 amendments to the procedural framework rule at issue in this proposal, which remain fairly recent and apply almost exclusively to internal Agency process. EPA seeks comment on the changes proposed in this action, including on whether stakeholders have any

significant reliance interests on the 2024 amendments at issue and, if so, how such interests should be accounted for in any final action.

C. *What action is the Agency proposing to take?*

EPA is proposing to amend the procedural framework rule that governs how the Agency conducts risk evaluations on existing chemical substances under TSCA section 6(b) (15 U.S.C. 2605(b)). These proposed amendments are specifically targeted towards changes made in the 2024 final rule that may not be consistent with the best reading of TSCA and that may impede the timely completion of risk evaluations and unnecessarily impair the effective and efficient protection of health and the environment. Provisions being reconsidered include whether TSCA necessitates a single risk determination for each chemical substance evaluated versus a risk determination for each condition of use of the given chemical substance, outlined in Unit III.B; whether EPA must evaluate all conditions of use and all exposure routes and pathways in a risk evaluation, outlined in Unit III.A.3; whether and how the use of personal protective equipment and engineering and administrative controls in an occupational work environment should be considered, outlined in Unit III.C.1; certain regulatory definitions and whether regulatory definitions should be broader than the statutory definitions, outlined in Unit III.D.2; and what process EPA should follow when reconsidering aspects of a risk evaluation, outlined in Unit III.E. EPA is also proposing certain amendments to the process and requirements that manufacturers (including importers) would be required to follow when they request an Agency-conducted TSCA risk evaluation on a particular chemical substance, outlined in Unit III.F.

Specifically, EPA is proposing to amend the regulations at: 40 CFR 702.31 so that the changes to the procedures as part of this rulemaking would be applied to all risk evaluations initiated on or after the date of the final rule and would be applied to risk evaluations that are in process as of the date of the final rule, but not yet finalized, to the extent practicable; 40 CFR 702.33 to revise or add definitions to ensure transparency and accountability in conducting risk evaluations; 40 CFR 702.37 and 40 CFR 702.39 to remove provisions in the 2024 final rule that

require EPA to consider every condition of use and every exposure route and pathway based on reasonably available information without exception when conducting a risk evaluation under TSCA section 6(b); 40 CFR 702.39, to return to the risk determination approach in the 2017 final rule, which required EPA to make a determination of unreasonable risk for each condition of use instead of a single risk determination on the chemical substance as a whole, and to further clarify how EPA will take occupational exposure controls into account when conducting risk evaluations and making risk determinations; 40 CFR 702.43 to revise procedures established in the 2024 final rule for whether and how EPA would endeavor to revise or supplement final scope documents and draft or final risk evaluations; and 40 CFR 702.45 to generally scale back the information collection obligations that the 2024 final rule imposed on requesting manufacturers, and to clarify that manufacturers that withdraw a request before it is granted do not incur fees.

There are certain aspects of the current risk evaluation procedural regulations that EPA is not proposing to change, including the general revised organization of the regulations as amended in the 2024 final rule. EPA is not proposing to make edits to the definitions found in 40 CFR 702.33, some of which were changed in the 2024 final rule, except for those specifically called out in this proposal (e.g., overburdened communities). Further, EPA is not proposing to make changes to the general requirements (40 CFR 702.37) and components of risk evaluations (40 CFR 702.39), some of which were amended in the 2024 rule, except where changes are outlined in this proposal (e.g., deletion of 40 CFR 702.39(8) and (9)).

For risk evaluations initiated prior the effective date of the final rule, but not yet finalized, EPA will seek to apply the requirements to the extent practicable. These requirements shall not apply retroactively to risk evaluations already finalized.

EPA is requesting public comment on all aspects of this proposal.

D. *Why is the Agency proposing this action?*

As further explained in Units I, II, and III of this preamble, EPA has reviewed the May 3, 2024, final rule entitled *Procedures for Chemical Risk Evaluation Under the Toxic Substances*

Control Act (89 FR 37028, May 3, 2024) (FRL-8529-02-OCSPP) (Ref. 1) (hereinafter "2024 final rule"), which amended the July 20, 2017, final rule entitled *Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act* (82 FR 33726, July 20, 2017) (FRL-9964-38) (Ref. 2) (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;

• Executive Order 14219, "Ensuring Lawful Governance and Implementing the President's 'Department of Government Efficiency' Deregulatory Initiative," which directs agencies to initiate a process to review existing rules for consistency with law and Administration policy and to identify certain regulations for potential rescission or modification (90 FR 10583, February 19, 2025) (Ref. 3); and

• Executive Order 14303, "Restoring Gold Standard Science" (90 FR 22601, May 23, 2025) (Ref. 4).

As a result of this review, the Agency is proposing targeted amendments to the 2024 final rule and associated regulatory text.

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

The incremental impacts of this action are associated with revisions to procedural requirements, as described in Unit III.F of this preamble, that apply to manufacturers when manufacturers (including importers) voluntarily request that EPA perform a risk evaluation on a particular chemical substance. EPA has estimated the potential burden and costs associated with the proposed requirements for submitting such a request. These estimates of burden and costs are available in the docket (Ref. 5), discussed in Unit VI of this preamble, and briefly summarized here.

The total estimated annual burden is 166 hours and $91,831 (per year), which is based on an estimated per request burden of 166 hours.

EPA's evaluation of the potential costs associated with this action is discussed in Unit

VI.C of this preamble. Because this proposed action focuses on the activities that a manufacturer must perform in voluntarily requesting a risk evaluation, the estimated incremental costs to the public are expected to be negligible. However, there are Paperwork Reduction Act (PRA) related burden and costs if industry chooses to submit a manufacturer requested risk evaluation to the Agency. This rulemaking is expected to reduce the regulatory burden associated with these submissions resulting in an estimated PRA activity cost savings of $23,880 per year (assuming one submission per year) as compared to the 2024 final rule.

EPA specifically requests comment on the burden estimate and assumptions associated with the calculation associated with the burden (*e.g.*, number of requests EPA expects). More generally, EPA requests comment on whether and how the proposed rule would reduce burdens, and welcomes detailed information, examples, and data addressing the impacts of the rule.

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

EPA is requesting public comment on all aspects of this proposal. Throughout this proposed rule, the Agency is soliciting feedback from the public on specific issues. See Unit IV for a summary of those specific requests for comment.

1. *Submitting CBI.*

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

2. *Tips for preparing your comments.*

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

II. Background

TSCA section 6(b)(4)(B) requires EPA to establish, by rule, a process to conduct risk evaluations that meet applicable statutory requirements (15 U.S.C. 2605(b)(4)(B)). EPA originally promulgated the procedural framework rule for risk evaluations under TSCA section 6(b)(4)(B) in 2017 and subsequently revised the procedural framework rule in 2024. This Unit summarizes the background for this proposed rule, including the 2017 final rule, judicial review of the 2017 final rule, the 2024 final rule, and EPA's review of the 2024 final rule in consideration of the Administration's priorities and recent judicial decisions on statutory interpretation, including the Supreme Court's decision in *Loper Bright Enterprises v. Raimondo*, 603 U.S. 369 (2024).

A. *The 2017 Final Rule*

As amended by the 2016 Frank R. Lautenberg Chemical Safety for the 21st Century Act (Pub. L. 114-182, 130 Stat. 448) (Lautenberg Act), TSCA section 6(b)(4)(B) requires EPA to establish, by rule, a process to conduct risk evaluations in accordance with statutory requirements (15 U.S.C. 2605(b)(4)(B)). Specifically, Congress directed EPA to use this process to "determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use" (15 U.S.C. 2605(b)(4)(A)). TSCA sections 6(b)(4)(A) through (H) enumerate the deadlines and minimum requirements applicable to this process, including provisions that direct which chemical substances must undergo risk evaluation, the development of criteria for manufacturer-requested risk evaluations, the minimum components of an Agency risk evaluation, and the timelines for public comment and completion of the risk evaluation (15 U.S.C. 2605(b)(4)(A) through (H)). The statute also requires EPA to consider reasonably available information and operate in a manner that is consistent with the best available science and make decisions based on the weight of the

scientific evidence (15 U.S.C. 2625(h), (i), (k)).

Accordingly, on July 20, 2017, EPA promulgated a final rule that established the process for conducting risk evaluations under TSCA section 6(b). The 2017 final rule identified the components of the risk evaluation process applicable to a chemical substance or category of chemical substances including: scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. For the unreasonable risk determination, the 2017 final rule at 40 CFR 702.47 stated that "EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of uses [sic] within the scope of the risk evaluation." This process was intended to be used for the initial ten chemicals identified for evaluation, for chemical substances designated as high-priority substances during the prioritization process under TSCA section 6(b)(1), and for those chemical substances for which EPA has initiated a risk evaluation in response to a manufacturer request.

While the regulatory text of the 2017 final rule did not directly address the risk evaluation scope decisions that EPA might make, EPA explained in the preamble that it interpreted the requirements of TSCA section 6 to apply to conditions of use for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur, rather than to legacy uses, which EPA used as a term for continuing, *in-situ* uses of chemicals for which manufacturing, processing, or distribution in commerce had ceased (e.g., certain phased-out flame retardants present in textiles or furniture that continue to be used, asbestos-containing pipe wrap, etc.), associated disposal (disposal of legacy uses), or legacy disposals (disposals that had already occurred). Therefore, EPA provided that it would not include legacy uses, associated disposals, or legacy disposals of a chemical in the scope of a risk evaluation on that chemical. The 2017 final rule also included various other provisions, such as requirements for the form and content of manufacturer requests for risk evaluations, a provision indicating that manufacturer-submitted information would be held to the scientific standards in

TSCA section 26(h), and a provision establishing that the submission of inaccurate, incomplete, or misleading information pursuant to a manufacturer-requested risk evaluation is a prohibited act subject to penalties under Title 18 of the U.S. Code.

B. *Judicial Review of the 2017 Final Rule*

Several non-governmental organizations filed petitions for judicial review of the 2017 final rule, which were consolidated in the U.S. Court of Appeals for the Ninth Circuit as *Safer Chemicals, Healthy Families v. EPA* on August 10, 2017 (Ref. 6). The Ninth Circuit issued a decision on November 14, 2019, holding that EPA's exclusion of "legacy uses and associated disposals" from the conditions of use that the Agency would consider in any risk evaluation was not consistent with the law in that the TSCA definition for condition of use clearly includes uses and future disposals. 943 F.3d 397, 425 (9th Cir. 2019) (Ref. 6). At EPA's request, the Ninth Circuit concurrently (1) vacated and remanded the rule provisions applying criminal penalties to the submission of inaccurate or incomplete information to EPA pursuant to a manufacturer-requested risk evaluation, and (2) remanded without vacatur the rule provisions addressing the information requirements for, and application of the TSCA section 26 scientific standards to, a manufacturer-requested risk evaluation. *Safer Chems., Healthy Families v. EPA*, 791 F. App'x 653, 656 through 657 (9th Cir. 2019) (Ref. 7).

The Court declined to rule on several other challenges raised by the petitioners, including the argument that the 2017 final rule improperly required EPA to make risk determinations for each condition of use rather than a single risk determination for the chemical substance and the argument that the 2017 final rule improperly granted EPA the discretion to exclude certain conditions of use from the scope of a risk evaluation. The Court reasoned that petitioners' arguments were not justiciable because it was unclear "whether the Agency will actually conduct risk evaluations in the manner [those litigants] fear[ed]." *Safer Chems.*, 943 F.3d at 413. (Ref. 6). With regard to petitioners' claim that EPA intended to exclude conditions of use out of the scope of the risk evaluations, the court held that claim not ripe and did "not interpret the language in

the [2017 final rule] to say anything about exclusion of conditions of use." *Id.* at 420 (Ref. 6).

C. *The 2024 Revisions to the 2017 Final Rule*

After a change in Administration, President Biden issued Executive Order 13990 on January 20, 2021 (86 FR 7037, January 25, 2021) (Ref. 8) which instructed agencies to review and consider revising regulations finalized by the prior Administration according to a new set of environmental policies. In response to the Executive Order, EPA announced certain policy changes for TSCA risk evaluations on June 30, 2021, including expanded consideration of exposure pathways, constraints on EPA's assumptions regarding personal protective equipment ("PPE") use, and making risk determinations on the "whole chemical," rather than on individual conditions of use (Ref. 9).

In consideration of Executive Order 13990, EPA issued a Notice of Proposed Rulemaking on October 30, 2023 (*Procedures for Chemical Risk Evaluation Under the Toxic Substances Control Act (TSCA)*, 88 FR 74292, October 30, 2023 (FRL-8529-01-02-OCSPP)) (hereinafter "2023 proposed rule") (Ref. 10), that included the policy changes identified in 2021, the changes EPA determined necessary to make the rule consistent with the Ninth Circuit's decision in *Safer Chemicals*, and a number of other proposed revisions. During a 45-day public comment period, public commenters raised a multitude of issues, including but not limited to concerns about the proposed expanded consideration of exposure pathways, proposed constraints on EPA's assumptions regarding personal protective equipment ("PPE") use, and EPA's proposal to make risk determinations on the "whole chemical," rather than on individual conditions of use as detailed in EPA's Response to Comment Document on the 2023 proposed rule (Ref. 11). EPA issued the 2024 final rule on May 3, 2024 (89 FR 37028) (FRL-8529-02-OCSPP) (Ref. 1). Provisions of the 2024 final rule being reconsidered in this proposed action are described in this Unit and in Unit III.

The 2024 final rule codifies provisions requiring EPA to consider all exposure pathways, including those covered by other statutes such as the Clean Air Act and the Clean Water Act, and

to include all reasonably known conditions of use within the scope of the risk evaluation, based on an interpretation of TSCA section 6(b)(4) that limits EPA's discretion on scoping of risk evaluations. Likewise, the 2024 final rule interprets TSCA section 6(b)(4)(A) to require that EPA make a single determination of unreasonable risk for the entire chemical substance rather than a risk determination for each individual condition of use assessed. The 2024 final rule also requires EPA to consider "reasonably available information, including known and reasonably foreseen circumstances where subpopulations of workers are exposed due to ineffective use of personal protective equipment," and that the Agency "not consider exposure reduction based on assumed use of personal protective equipment as part of the risk determination" 40 CFR 702.39(f)(2). This regulatory language is based in part on the possibility of noncompliance with Occupational Safety and Health Administration (OSHA) standards, purported gaps or limitations in OSHA coverage, and lessons learned from the Agency's implementation of the risk evaluation program to date (89 FR 37028, May 3, 2024) (FRL-8529-02-OCSPP) (Ref. 1, at p. 37037).

The 2024 final rule also amended requirements for manufacturer-requested risk evaluations for the stated reason of assisting EPA in identifying conditions of use and collecting hazard and exposure information for the requested chemical substances. Under the 2024 final rule, manufacturers requesting risk evaluations bear the burden of providing EPA with all of the information necessary to conduct the risk evaluation. The revisions require manufacturers to gather and provide all such information that is known to, or reasonably ascertainable by them. The 2024 final rule explains that manufacturers must exercise due diligence in collecting this information, which includes a thorough search of publicly available information, an inquiry throughout the manufacturer's entire organization, and inquiries to upstream suppliers, downstream users, and employees and other agents of the manufacturer. The 2024 final rule, at 40 CFR 702.45(a)(4), generally holds manufacturer-requested risk evaluations to the same information standards as EPA-initiated risk evaluations, which would preclude limited risk evaluations on a subset of the conditions of use of interest to the requesting manufacturers.

Other revisions related to the 2021 policy changes included the addition of the phrase "overburdened communities" to the definition of the term "potentially exposed or susceptible populations"; the definition in the 2017 final rule had simply repeated the definition in the statute. In addition, the preamble to the 2024 final rule discussed EPA's intention to adhere to the Ninth Circuit's decision in *Safer Chemicals,* 943 F.3d 397 (Ref. 6), and to include legacy uses and associated disposals in a "part 2" risk evaluation for asbestos, as well as in future risk evaluations.

Provisions of the 2024 final rule not directly related to the 2021 policy change announcement included language on the process EPA will follow to revise risk evaluation scope documents and other risk evaluation documents. These include final risk evaluations, which would generally require EPA to reinitiate the prioritization process under 40 CFR 702.7 for the chemical substance, unless EPA determines that it is in the interest of protecting human health or the environment to proceed immediately with substantively revising the risk evaluation. The 2024 final rule also committed EPA to either performing an aggregate exposure assessment in each risk evaluation or explaining why it had not done so.

With respect to regulatory definitions, the 2024 final rule removed the definitions of "best available science" and "weight of the scientific evidence," and incorporated the statutory considerations related to the term "best available science" elsewhere in the regulation. Minor amendments to the definitions of the terms "pathways," "routes," "aggregate exposure," and "sentinel exposure" were made to align with Agency phraseology and guidance, and to clarify that aggregate and sentinel exposures can apply to individuals and communities. The 2024 final rule also included additional clarifications and a reorganization of the sections in 40 CFR part 702, subpart B. More information on these amendments can be found in the preamble to the 2024 final rule.

Petitions for review of the 2024 final rule were filed by industry stakeholders, a union, and environmental advocacy organizations. *See United Steel, et al. v. EPA*, No. 24-1151 (D.C.

Cir.). The litigation was consolidated in the U.S. Court of Appeals for the D.C. Circuit Court and is currently in abeyance while EPA reconsiders the 2024 final rule.

D. *Review of the 2024 Final Rule*

Following another change in Administration, President Trump revoked EO 13990 on January 20, 2025 (90 FR 8353) (Ref. 12) and issued Executive Order 14219 on February 19, 2025, which directs agency heads to review all regulations under their jurisdiction for consistency with law and Administration policy and identify inconsistent regulations for recission or modification (90 FR 10583) (Ref. 3). Among the categories of regulations to be identified are those that are based on anything other than the best reading of the underlying statutory authority; those that significantly and unjustifiably impede technological innovation, infrastructure development, disaster response, inflation reduction, research and development, economic development, energy production, land use, and foreign policy objectives; and those that impose undue burdens on small business and impede private enterprise and entrepreneurship.

On March 10, 2025, Administrator Zeldin identified the 2024 final rule as one such regulation under review and announced that EPA would be conducting a rulemaking to review multiple aspects of the 2024 final rule for consistency with law and Administration policy (Ref. 13). The Administrator also described the importance of the activity under TSCA to review chemicals already in commerce, supporting his initiative for clean air, land and water for every American, as well as advancing permitting reform, cooperative federalism and cross-agency partnerships by better integrating the best workplace standards from across the Federal government and industry and meeting TSCA's tight timelines for risk evaluations. Specific aspects of the 2024 final rule mentioned in the Administrator's March 10, 2025, press release include whether EPA must evaluate all of the conditions of use of a chemical substance, the single risk determination requirement, whether and how the use of PPE and industrial controls in an occupational work environment should be incorporated into risk evaluations, and whether

terms should be more broadly defined in the regulation than they are in the statute (Ref. 13).

Soon after the 2024 final rule was published, the Supreme Court issued its decision in *Loper Bright*. In that case, the Court held that when interpreting statutes administered by federal agencies, courts must abandon the two-step framework in *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842 through 843 (1984), and instead use ordinary tools of statutory interpretation to identify and apply the single best reading of the statute at issue. *Loper Bright*, 603 U.S. 369 at 400. EPA believes that certain provisions of the 2024 final rule are not based on the best reading of TSCA and are thus impermissible under the Court's decision in *Loper Bright*.

In addition, as discussed in more detail in Unit III of this preamble, EPA's preliminary review of the 2024 final rule found that certain aspects of the rule, such as the requirement to evaluate all conditions of use and all exposure routes and pathways in a risk evaluation, could negatively impact EPA's ability to complete risk evaluations in a timely manner. EPA also found that other aspects of the rule, such as the single risk determination requirement, could negatively impact technological innovation, small business, and private enterprise and entrepreneurship.

Thus, this proposal reflects the results of EPA's targeted review of these aspects of the 2024 final rule and selected other provisions as described in Unit III of this preamble. EPA is not proposing to amend provisions included in the 2024 final rule that are not outlined in Unit III, and requests comment whether it should revisit other aspects of the 2024 final rule. This proposal is also deregulatory in nature, in that it would reduce the regulatory burden associated with the information a manufacturer would have to provide with a manufacturer-requested risk evaluation.

III. Proposed Amendments

A. *Scope of TSCA Risk Evaluations*

1. *Introduction.*

EPA is proposing to remove provisions in the 2024 final rule that require EPA to consider each and every condition of use and each and every exposure route and pathway based

on reasonably available information when conducting a risk evaluation under TSCA section 6(b). Specifically, EPA is proposing to remove the phrase "EPA will not exclude conditions of use from the scope of the risk evaluation" from 40 CFR 702.37(a)(4), combine the remaining text with subparagraph (a)(3), and remove 40 CFR 702.39(d)(9) in its entirety. The Lautenberg Act (Pub. L. 114-182, 130 Stat. 448) amended TSCA to direct EPA to conduct comprehensive risk evaluations, a more efficient process for EPA to evaluate the large number of existing chemical substances than the piecemeal approach that EPA had taken previously in several cases, but also provided EPA with some discretion regarding which conditions of use, exposure routes, and exposure pathways it will consider in risk evaluation (Ref. 14 at p. 3519).

When TSCA was originally signed into law in 1976, there were tens of thousands of chemicals in commerce and, while the law gave EPA authority to conduct assessments to determine whether those existing chemicals present unreasonable risk of injury to health or the environment, TSCA did not specifically require that EPA do so (88 FR 74292, October 30, 2023) (Ref. 10 at p. 74296). EPA did conduct risk assessments on a handful of these existing chemicals prior to 2016, but most of those assessments were focused on a specific subset of chemical uses (*e.g.*, paint and coating removal, vapor degreasing) being evaluated at the time. This approach to assessing existing chemicals, taken under the original TSCA, along with other aspects of the TSCA authorities regarding existing chemicals, failed to inspire public confidence in the safety of chemicals present in our households, communities, and the environment (88 FR 74292, October 30, 2023) (Ref. 10 at p. 74296).

The 2016 amendments to TSCA were designed to address this lack of confidence. One of the defining features of the amendments was the mandate for EPA to methodically prioritize those thousands of existing chemicals for review, and then to evaluate their risks under the chemical's "conditions of use," *i.e.*, "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of" (15 U.S.C. 2602(4)).

While clearly a significant undertaking, Congress recognized that meaningful progress on evaluating the universe of thousands of existing chemicals would necessitate such a mandate, along with deadlines for completing the work (Ref. 14). A continuation of the pre-2016 approach to risk evaluation and risk management for this universe of chemicals would be inefficient and would further delay progress in the overall undertaking.

Completing these comprehensive risk evaluations within the timeframes set forth by Congress, only 3 to 3.5 years, represents a significant ongoing challenge for EPA. EPA believes that risk evaluations under TSCA cannot be so complex or procedurally cumbersome that they cannot reliably be completed within the statutory timeframes. At the same time, EPA also believes it should not routinely produce partial or incomplete TSCA risk evaluations. In order for TSCA implementation efforts to be sustainable while also meeting the statutory timeframes for completing evaluations, EPA believes risk evaluations must be fit-for-purpose such that the Agency meets both the substantive statutory and regulatory requirements for conducting risk evaluations, while completing those evaluations within the statutory deadlines. Further, the statute provides EPA with discretion as to the "hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider" in a risk evaluation under TSCA (15 U.S.C. 2065(b)(4)(D)) as well as on the level of evaluation expected for each aspect of the risk evaluation.

EPA believes that risk evaluation scoping decisions are highly fact-specific and are made on a case-by-case basis. EPA intends to generally explain its scoping decisions in the draft scope document or the draft risk evaluation, as appropriate. EPA intends to continue to release draft scope documents and draft risk evaluations for public comment, to provide multiple opportunities for stakeholders to review scoping decisions. In addition, TSCA section 19 provides for judicial review of such decisions, which must be based on substantial evidence in the rulemaking record taken as a whole (15 U.S.C. 2618).

2. *Conditions of use*.

EPA proposes that there are two different types of discretion involved in considering the scope of a risk evaluation with regard to conditions of use. First, early in the TSCA section 6(b) process, EPA must determine what the conditions of use are for a candidate chemical substance. That is, "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)). The decision as to whether a circumstance is "intended, known, or reasonably foreseen" to occur necessarily involves the exercise of discretion, particularly as to whether an intention to take an action exists, or whether an occurrence is reasonably foreseeable. Second, once a particular circumstance is determined to be a condition of use, EPA has discretion to exclude it from the scope of the risk evaluation under TSCA section 6(b)(4)(D) (15 U.S.C. 2605(b)(4)(D)). The question whether the Agency has discretion under TSCA to exclude that condition of use from the scope of a risk evaluation has been the source of much discussion publicly, particularly during the development of the 2017 and 2024 final rules. While EPA agrees with the goal of the TSCA amendments to establish a systematic approach to reviewing and addressing potential risks posed by chemicals already in commerce, it also believes that eliminating the Administrator's discretion to determine which conditions of use are included in the risk evaluation is neither mandated by the statute nor workable, given the magnitude of the task.

In the 2017 final rule EPA expressed that it had discretionary scoping authority (82 FR 33726, July 20, 2017) (Ref. 2 at p. 33729). In support of this assertion of discretionary scoping authority in the 2017 final rule, EPA pointed to language in TSCA section 6(b)(4)(D) that requires the Agency to identify the conditions of use in a scope document that the Agency "expects to consider" in a risk evaluation and the "as determined by the Administrator" phrasing in the statutory definition of "conditions of use" itself (*id*. at 33729). EPA argued that such language gave the Agency discretion to select among the conditions of use and, ultimately, to exclude conditions of use from the scope of TSCA risk evaluations. EPA expressed at that time

that those provisions empowered the Agency to exclude, for example, conditions of use that the Agency deemed "*de minimis*" in nature, or conditions of use where opportunities for exposure were likely to be limited (e.g., closed system or intermediate) (*id.* at 33729). The 2017 final rule cited excerpts from the Senate's discussion of the House/Senate Conference Report in support of EPA's contention that EPA had some discretion to determine the scope of risk evaluations (*id.* at 33728). As described by Senator Vitter, one of the Senate Sponsors of the legislation, this discretion "assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess and control priority chemicals and meet the new law's strict deadlines" (Ref. 14 at p. 3519). For purposes of this proposed action, EPA agrees with this statement on the focus and goals of TSCA section 6(b) risk evaluations. In exercising the scoping discretion proposed in this action, EPA would not generally intend to exclude circumstances that the reasonably available information indicates would raise the greatest potential for risk.

EPA further proposes that experience in conducting risk evaluations under TSCA section 6(b) has made clear that at least some discretion to tailor the scope of risk evaluations is necessary to accomplish the objective of making meaningful progress in comprehensively evaluating the risks presented by existing chemicals while also complying with TSCA's ambitious statutory deadlines. As mentioned in the 2017 final rule, excluding *de minimis* uses and uses with minimal exposure potential are two examples of how EPA might choose to focus risk evaluations.

Byproducts are another example. The regulatory definition of "manufacture for commercial purposes" includes chemical substances that are produced coincidentally during the manufacture, processing, use, or disposal of another chemical substance or mixture, including both byproducts that are separated from that other substance or mixture and impurities that remain in that chemical substance or mixture. Such byproducts and impurities may, or may not, in themselves have commercial value (e.g., 40 CFR 704.3, 40 CFR 720.3). As explained in the

2017 final rule, in some instances, it may be most appropriate from a technical and policy perspective to evaluate the potential risks arising from a chemical impurity within the scope of the risk evaluation for the impurity itself. In other cases, it may be more appropriate to evaluate such risks within the scope of the risk evaluation for the separate chemical substances that bear the impurity (82 FR 33726, July 20, 2017) (Ref. 2 at p. 33729). EPA believes that this is generally the better approach for most chemical substances, because the risks of the parent chemical and its byproducts will be evaluated and managed together. In contrast, for example, although EPA set out to conduct the risk evaluation for 1,4-dioxane by excluding byproducts, stating that EPA would consider unintentional 1,4-dioxane production in the risk evaluations of its various parent chemicals (Ref. 15), EPA has since decided that the risks of 1,4-dioxane production as a byproduct are best assessed in the same risk evaluation as the other conditions of use of 1,4-dioxane (Refs. 15 and 16). In the case of 1,4-dioxane, the parent chemicals are a diverse group, many of which are not considered hazardous, including surfactants that have appeared on EPA's Safer Chemical Ingredients List, which represents a list of chemical ingredients EPA has evaluated and determined to be safer than traditional chemical ingredients (Ref. 17). This discretion to decide where to evaluate risks from byproducts, whether in the risk evaluation for the chemical substance itself or in the risk evaluation for the parent chemical, is necessary for this ambitious program to work as intended.

Although EPA asserted in the 2024 final rule that it has no discretion to exclude conditions of use from the scope of a risk evaluation, the preamble also acknowledged that the Agency retains the authority to exercise judgment in making its determination as to whether a particular circumstance is intended, known, or reasonably foreseen, and therefore falls within the definition of "condition of use" for a particular chemical (89 FR 37028, May 3, 2024) (Ref. 1 at pp. 37032 through 37033). EPA further explained in the 2024 final rule that the Agency has and will continue to undergo a process to determine each chemical's conditions of use, analyzing reasonably available information and applying the facts, Agency expertise and professional

judgment on a case-by-case basis. The 2024 final rule states that, when information suggests that a circumstance of manufacture, processing, distribution in commerce, use or disposal is known to be occurring, or 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.

EPA's approach in the 2024 final rule to determining both the conditions of use for a chemical substance and the scope of the risk evaluation for the substance effectively eliminates the Agency's discretion in scoping in favor of using the "intended, known, or reasonably foreseen" language from the statutory definition of the term "conditions of use" to achieve an appropriately-scoped risk evaluation. Pursuant to the Supreme Court's decision in *Loper Bright* EPA believes that TSCA is best read as permitting the Agency to exercise discretion under TSCA section 3(4) in determining what constitutes a condition of use, as well as discretion under TSCA section 6(b)(4)(D) in determining what conditions of use EPA expects to consider in a risk evaluation, recognizing that the statute clearly envisions comprehensive risk evaluations. EPA continues to believe that TSCA section 3(4) provides the Agency with discretion to determine whether a use falls under the two buckets: (1) known, intended, or reasonably foreseen, and (2) manufactured, processed, distributed in commerce, used, or disposed of. Under the interpretation proposed in this action, if EPA determines that a use falls into each of these buckets, the Agency would conclude that the use is a condition of use. Next, the Agency would determine in its discretion under TSCA section 6(b)(4)(d) whether EPA "expects to consider" the given condition of use in the risk evaluation. This reading avoids the need to stretch the Agency's discretion in TSCA section 3(4) in order to exclude certain uses of a chemical, such as the unintentional byproduct example above, while still maintaining EPA's ability to ensure an appropriately scoped risk evaluation.

In the preamble to the 2023 proposed rule, EPA also discussed the Ninth Circuit's *Safer Chemicals* decision on legacy use, associated disposal, and legacy disposal (88 FR 74292, October 30, 2023) (FRL-8529-01-OCSPP) (quoting *Safer Chems.*, 943 F.3d at 425 through 426)

(Ref. 10 at p. 74298). As the Agency explained at the time, the 2017 final rule identified legacy disposal as falling outside the statutory definition of "conditions of use" because EPA interpreted the definition as focusing on circumstances that are prospective or on-going, rather than reaching back to evaluate risks associated with "legacy disposal" (i.e., disposal that has already occurred). The Ninth Circuit agreed that "legacy disposal" falls outside the statutory definition of conditions of use, reasoning that a substance that has already been disposed of will not ordinarily be intended, known, or reasonably foreseen to be used again (*Safer Chems.*, 943 F.3d at 425 through 427) (Ref. 6). However, the court additionally held that EPA could not categorically exclude legacy uses and associated disposals from the definition of "conditions of use" because they represent future use and disposals that do clearly fall within the statutory definition of condition of use (*id.* at 424 through 425) (Ref. 6). The court reasoned that to the extent that these are prospective use and disposal of a chemical substance that are intended, known, or reasonably foreseen, they "unambiguously fall within TSCA's definition of 'condition of use,'" regardless of whether there is ongoing upstream manufacture, processing, or distribution in commerce (*id.* at 424 through 425). According to the 2017 final rule, a legacy use is the continued use of a product, such as in-place asbestos insulation, after manufacturing has ceased, and an associated disposal is the disposal of a legacy use product (82 FR 33726, July 20, 2017) (Ref. 2 at p. 33729).

As explained in the preamble to the 2024 final rule, EPA has committed to complying with the *Safer Chemicals* decision and continues to exclude legacy disposals, but not legacy uses or associated disposals, from the statutory definition of "conditions of use." (89 FR 37028, May 3, 2024) (Ref. 1 at 37032). EPA includes this information as background and does not propose to revisit or revise its position on the matter.

EPA is proposing to delete the phrase "EPA will not exclude conditions of use from the scope of the risk evaluation" from 40 CFR 702.37(a)(4) and combine, "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," with 40 CFR 702.37(a)(3). The revised subparagraph (a)(3) would read as follows:

> 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 technically sound determinations as to whether each condition of use presents an unreasonable risk of injury to health or the environment, based on the weight of the scientific evidence. 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 conditions of use in any risk evaluation will vary as necessary to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under that condition of use.

As discussed in this Unit, EPA agrees that the amended TSCA requires the Agency to conduct comprehensive risk evaluations, not multiple risk evaluations for the same chemical, a handful of conditions of use at a time. However, without the ability to decide where unintentional byproduct manufacture will be evaluated, for example, or whether an activity need not be assessed because it is unlikely to result in exposures to a chemical substance, EPA will be unable to focus its risk evaluations on the conditions of use that have the greatest potential for risk and thereby effectively evaluate and manage risks while also meeting the statutory deadlines.

EPA requests comment on all aspects of its proposed amendments to 40 CFR 702.37(a)(3) and (4), including whether the revisions are sufficiently clear as to EPA's intent regarding appropriately scoped, fit-for-purpose risk evaluations under TSCA section 6(b). Based on additional information submitted to EPA, the Agency also considered alternative provisions regarding the scope of TSCA risk evaluations that the Agency is not proposing to include in this action but is instead requesting comment on. Specifically, EPA requests comment on whether a definition of "reasonably foreseen" would enhance the transparency and predictability of EPA's decisions on the circumstances of manufacture, processing, distribution in commerce, use, or disposal that constitute conditions of use. EPA would likely draw a definition from the

considerations outlined by EPA's new chemicals program under section 5 of TSCA (Ref. 18, at footnote 1). EPA also requests comment on whether this rule should provide more specific considerations that EPA will use in determining which conditions of use are within the scope of the risk evaluation. Such considerations could include whether there is a reasonable potential for exposure to humans or the environment as a result of the condition of use, the extent to which the potential risks posed by a chemical impurity can be addressed in a risk evaluation for the separate chemical substance that bears the impurity, and the extent to which risk reduction opportunities are available for the condition of use. EPA requests comment on whether one of these considerations should be whether the substance is present at a *de minimis* level under the condition of use, and, if so, whether EPA should promulgate a definition of *de minimis*, recognizing that the toxicity of chemical substances vary. Finally, EPA is also interested in comments on how to address conditions of use that are identified after the conclusion of a risk evaluation on a chemical substance. As previously stated, EPA does not believe stakeholders have reliance interests pertaining to the process for future, yet-to-be-completed risk evaluations that will be carried out in accordance with this proposed rule, but seeks comments on any reliance interests commenters believe they have.

3. *Inclusion of all exposure pathways.*

In carrying out the first ten risk evaluations under TSCA, EPA appropriately scoped those evaluations by excluding analysis of certain exposures to the general population from releases to air, water, and land. The approach, which was not contemplated in the 2017 rule but was first articulated in ''Problem Formulation'' documents published in 2018 (after the Final Scope documents) for each of the first ten chemicals undergoing risk evaluation, premised on an argument that those pathways were already adequately assessed and managed – or could be adequately assessed and managed – under other EPA statutes and regulatory programs (Ref. 19 and 20). EPA further stated at that time that its intention was to use Agency resources efficiently under the TSCA program, avoid duplicating efforts taken pursuant to other Agency programs,

maximize scientific and analytical efforts, and meet TSCA's statutory deadlines for completing risk evaluations. In the final risk evaluations for the first ten chemicals, EPA excluded exposure pathways that could be covered by regulatory programs under the Clean Air Act (CAA), Clean Water Act (CWA), Safe Drinking Water Act (SDWA), Resource Conservation and Recovery Act (RCRA), and Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA) (e.g., drinking water pathways covered under the SDWA due to the existence of National Primary Drinking Water Regulations (NPDWRs) with chemical-specific, enforceable Maximum Contaminant Levels (MCL), or the inclusion of the chemical as an unregulated chemical on the Candidate Contaminant List (CCL)). EPA further asserted that this approach was supported by several TSCA authorities, including TSCA section 6(b)(4)(D), which in part directs the Agency to identify, in the scope document, the exposures that the Administrator "expects to consider" in the applicable risk evaluation, and TSCA section 9(b)(1), which allows the Administrator to use other EPA administered statutes to address risks to health or the environment, if the Administrator determines that these risks "could be eliminated or reduced to a sufficient extent" by actions taken under other EPA administered statutes (Ref. 15).

This approach was criticized by EPA's Science Advisory Committee on Chemicals (SACC) and several public commenters in comments on individual risk evaluation documents (Refs. 22, 23, and 24). In response to this and other external criticisms, EPA announced in June of 2021 that it would abandon this approach and subsequently developed the *Draft TSCA Screening Level Approach for Assessing Ambient Air and Water Exposures to Fenceline Communities Version 1.0* (Ref. 25). EPA used this screening level approach during development of risk management actions under TSCA section 6(a) to consider whether the conditions of use assessed in six of the first ten risk evaluations may have resulted in potential risks for nearby communities.

Further, EPA has consistently excluded from the scope of risk evaluations certain exposures that are associated with a condition of use, such as accidents, spills, leaks, and extreme

weather-related events like hurricanes and wildfires (89 FR 37028) (Ref. 1 at p. 37033); (82 FR 33726) (Ref. 2 at p. 33729). Therefore, EPA has consistently read TSCA to provide EPA with some discretion to exclude exposures. In the 2023 proposed amendments to the procedural framework rule, EPA indicated that if accidents, spills, leaks, or extreme weather-related events result in regular and predictable changes in exposures associated with a given condition of use of a chemical substance, such exposures would be known or reasonably foreseen and would be considered within the scope of the risk evaluation (88 FR 74292, October 30, 2023) (Ref. 10 at p. 74298). In the 2024 final rule, EPA added that it would consider whether exposures from accidents, spills, leaks, and weather-related events "would be regular or predictable, versus those that are unsubstantiated, speculative or otherwise not likely to occur" (89 FR 37028, May 3, 2024) (Ref. 1 at p. 37033). Regardless, whether exposures associated with such events might be reasonably foreseeable, EPA has determined that, in the absence of reasonably available information that shows that they are regular and predictable, it would be too difficult to assess and accurately characterize the risks associated with these events. Additionally, in May 2025 EPA denied a citizen's petition submitted under section 21 of TSCA for a section 6 rulemaking proceeding primarily because it was premised on the potential for accidental and catastrophic releases of a chemical which did not result in regular and predictable exposures. *See Hydrogen Fluoride; TSCA Section 21 Petition for Rulemaking Under TSCA Section 6; Reasons for Agency Response; Denial of Requested Rulemaking* (90 FR 20575, May 15, 2025).

In the 2024 final rule, EPA added a provision at 40 CFR 702.39(d)(9) that requires the Agency to "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." The rationale for this addition was that TSCA sections 6(b)(4)(D) and 9(b)(1) do not specifically authorize EPA to exclude exposure routes or pathways in the risk evaluation. Rather, EPA interpreted TSCA section 9(b)(1) as applying only to a subsequent risk management rulemaking action after the completion of a final risk evaluation. EPA concluded that the goal of the 2016 TSCA

amendments was to create more certainty and confidence in the safety of existing chemicals in the marketplace and asserted that this goal would not be furthered by evaluating a subset of a chemical substance's exposures or conditions of use.

In this action, EPA proposes to return to the approach taken in the first 10 risk evaluations by deleting 40 CFR 702.39(d)(9), thereby allowing EPA to exercise reasonable discretion in scoping a risk evaluation to ensure timely and efficient completion of risk evaluations. As discussed more extensively in Unit III.A.2 of this document, EPA now believes that TSCA section 6(b)(4)(D) is best read as permitting EPA some discretion as to the "hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to consider" in the risk evaluation. EPA proposes that this is the best interpretation of the statute and that this approach better fulfills statutory objectives by allowing EPA to focus its TSCA risk evaluations on the areas of greatest concern without conducting evaluations that are redundant of evaluations conducted by other EPA program offices. This is equally important, whether considering conditions of use or exposure routes and pathways. EPA proposes that meeting its obligations under the statutory scheme requires that the Agency have discretion to exclude exposure routes and pathways that the reasonably available information indicates are unlikely to result in exposures that exceed *de minimis* levels. Similarly, EPA proposes that meeting its obligations under the statutory scheme requires that the Agency have discretion to exclude exposure routes and pathways that have been or are being addressed by other EPA-administered statutes and programs in order to avoid duplicative assessments.

In the risk evaluations finalized in 2020 and early 2021, EPA explained that the instruction in TSCA section 9(b)(1) for the Administrator to "coordinate actions taken under [TSCA] with actions taken under other Federal laws administered [by EPA]" (15 U.S.C. 2608(b)(1)) provided additional support for EPA's position that it has discretion to tailor the scope of TSCA risk evaluations to focus on the areas of greater concern and to avoid duplicative assessments (*see,* e.g., Risk Evaluation for Methylene Chloride, sec. 1.4.2) (Ref. 21). EPA

asserted that further support is provided by the remaining text of TSCA section 9(b)(1), which allows EPA to address risk through statutory authorities other than TSCA "[i]f the Administrator determines that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by actions taken under the authorities contained in such other Federal laws" (Ref. 21). Intra-agency coordination is integral to ensuring that EPA actions are well-informed, effective, and efficient. EPA explained that such coordination "entails both an identification of risk, and a referral of any risk that could be eliminated or reduced to a sufficient extent under other EPA-administered laws to the EPA offices responsible for implementing those laws (absent a finding that it is in the public interest to protect against the risk by actions taken under TSCA)" (Ref. 21 at sec. 1.4.2.). EPA further explained that risks may be identified by EPA's Office of Pollution Prevention and Toxics (OPPT) or another EPA office, and the form of the identification could vary. For instance, OPPT may find that one or more conditions of use for a chemical substance present(s) a risk to human or ecological receptors through specific exposure routes and/or pathways through a quantitative or qualitative assessment of risk based on reasonably available information (which might include, e.g., findings or statements by other EPA offices or other federal agencies). Alternatively, risk could be identified by another EPA office. For example, another EPA office administering non-TSCA authorities may have sufficient data to indicate that a particular condition of use presents risk to certain human or ecological receptors, based on expected hazards and exposures. This risk finding could be informed by information made available to the relevant office under TSCA section 9(e), which supports cooperative actions through coordinated information-sharing.

Upon further reflection, EPA believes that TSCA section 9(b)(1) is best read as supporting the Agency's discretion to scope risk evaluations in a manner that reflects existing activities of its other program offices, consistent with the approach taken in the 2020-2021 risk evaluations under the 2017 final rule (*see,* e.g., Ref. 21). For exposure pathways and risks that

fall under the jurisdiction of other EPA programs, such as those under the CAA or SDWA, EPA's proposal to delete 40 CFR 702.39(d)(9) will allow the Agency to coordinate risk evaluation and risk management activities under TSCA with activities under other programs and to tailor its risk evaluations under TSCA to facilitate that coordination. It is not an efficient use of EPA resources to evaluate exposure routes and pathways under TSCA that have been evaluated and are being managed by other EPA offices, or that could be more effectively and efficiently assessed and managed by other EPA offices. EPA proposes that nothing in TSCA's text or structure requires such a result and that duplicative assessments are contrary to the purpose of TSCA section 9(b) as amended in 2016 (*see* H. Rep. No. 114-176 at p. 28 (stating that the 2016 TSCA amendments "reinforce TSCA's original purpose of filling gaps in Federal law," and citing new language in section 9(b)(2) intended "to focus the Administrator's exercise of discretion regarding which statute to apply and to encourage decisions that avoid confusion, complication, and duplication")) (Ref. 26). So, for example, if EPA began a TSCA risk evaluation on a chemical substance that is also regulated as a Hazardous Air Pollutant under CAA section 112(42 U.S.C. 7412), 40 CFR 702.39(d)(9) currently would require another robust assessment of the potential risks to the general population through ambient air exposures.

EPA proposes that such duplication is not what Congress intended in amending TSCA in 2016. Under this proposed rule, when an exposure pathway of a chemical substance is not already evaluated and managed by another EPA program, EPA may assess the particular exposure pathway under TSCA. If EPA finds unreasonable risk, then it intends to, pursuant to TSCA section 9(b), coordinate risk management under the other EPA-administered statute when EPA determines that such risk can be eliminated or reduced to a sufficient extent by another EPA-administered statute, unless EPA determines it is in the public interest to take action under TSCA. Likewise, when a condition of use of a chemical substance is not evaluated, managed, or both, by another Federal Agency, EPA intends to evaluate the condition of use and determine whether it presents unreasonable risk. If EPA makes an unreasonable risk finding, it will, in its

discretion, follow the procedures of TSCA section 9(a) to coordinate risk management.

EPA requests comments on all aspects of its proposed changes to 40 CFR 702.37(a) and 702.39(d) that relate to the conditions of use and the exposure routes and pathways assessed in TSCA section 6(b) risk evaluations. EPA also requests comment on whether this rule should provide more specificity on EPA's coordination activities under TSCA section 9, such as a requirement to document consultations with other Federal agencies on draft scope documents and draft risk evaluations. EPA requests comment on how EPA should consider, for TSCA section 6(b) risk evaluation purposes, existing federal statutes and regulations and risk assessments performed by other governmental entities. EPA requests comment on whether the Agency should include regulatory text, such as text that specifies that EPA has discretion to exclude conditions of use as well as exposure pathways and routes. Further, EPA requests comment on specific instances where EPA should exercise its authority to exclude conditions of use and exposure pathways and routes. EPA also requests comment on whether to add regulatory text that states that EPA can coordinate actions with other federal laws administered by EPA to ensure that chemical risks "could be eliminated or reduced to a sufficient extent" by other EPA actions, pursuant to TSCA section 9(b). Finally, EPA welcomes suggested regulatory text that could be considered. EPA is not currently aware of any significant reliance interests in the 2024 amendments regarding these proposed changes, given the 2024 amendments are fairly recent and apply almost exclusively to internal Agency process.

B. *Risk Determinations*

The 2024 final rule included a number of revisions to regulatory provisions on unreasonable risk determinations that EPA is now proposing to modify. Specifically, EPA is proposing to revise 40 CFR 702.39(f)(1) to return to the risk determination approach in the 2017 final rule and original 2020-2021 risk evaluations, which determined whether each condition of use of a chemical substance presents unreasonable risk. As discussed in this Unit, EPA believes that the provision in the 2024 final rule that requires EPA to make a single risk determination on

the chemical substance as a whole, rather than determinations on the conditions of use, is not consistent with the best reading of TSCA section 6, the Supreme Court's decision in *Loper Bright*. More specifically, this proposal would replace the current regulatory text with language that more closely tracks the version of 40 CFR 702.47 promulgated in the 2017 final rule. The new 40 CFR 702.39(f)(1) would read as follows: "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use by making separate risk determinations for each condition of use within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." EPA is also proposing to revise 40 CFR 702.39(f)(3), which would be superfluous, given that a risk determination would be made for each condition of use. The rationale for these proposed changes is discussed in this Unit. Proposed revisions to subparagraph (f)(2) are discussed in Unit III.C.1 of this preamble.

1. *Background.*

In each risk evaluation under TSCA section 6(b), EPA must determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other non-risk factors, under the conditions of use. In making a risk determination, EPA must evaluate relevant risk-related factors, including, but not limited to: the severity of the hazard (e.g., the nature of the hazard and irreversibility of the hazard); exposure-related considerations (e.g., duration, intensity, and frequency of exposure); the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); and the confidence in the information used to inform the hazard and exposure values. This includes an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. Descriptions of risk estimates that are based on highly refined hazard and exposure information would be considered differently than risk estimates based on compounding conservative assumptions on both hazard and exposure. The process of determining unreasonable risk is made on a case-by-case basis, given the

inherently unique nature of risk evaluations, and benchmarks are not treated as bright lines.

In proposing the 2017 rule (82 FR 7562, January 19, 2017) (Ref. 27), EPA included a regulatory provision on unreasonable risk determinations that largely mirrored the language of TSCA section 6(b)(4)(A) and clarified that the phrase "under the conditions of use" meant the conditions of use identified in the final scope document published for the chemical substance. EPA also included an exception in the 2017 final rule that would allow EPA to make an "early determination" for any specific condition of use that the Agency had sufficient information to find that it presents an unreasonable risk. Where such an early determination was made, the Agency could initiate risk management under TSCA section 6(a) for that specific condition of use immediately without waiting for the completion of the risk evaluation for all covered conditions of use of the chemical substance, which often takes multiple years (Ref. 27 at pp. 7568 and 7578).

EPA received comments on the 2017 proposed rule asserting that such early determinations of unreasonable risk for particular conditions of use was unfair and represented an inherent bias "toward Risk Evaluation outcomes that require regulatory actions" (Ref. 28). These commenters encouraged the Agency to extend this concept of early risk determinations to conditions of use found not to present an unreasonable risk (Ref. 29 at p. 47). Other commenters discouraged the Agency from allowing early determinations for conditions of use that do not present unreasonable risk. According to these commenters, a determination that a condition of use does not present unreasonable risk cannot be made until the risks of all conditions of use have been evaluated. One commenter argued that, while it is possible to conclude that a chemical substance presents an unreasonable risk based on the evaluation of a subset of uses before all of the conditions of use are evaluated, the reverse is not true. The same commenter also expressed concern over the potential for an early determination that a particular condition of use does not present unreasonable risk foreclosing the possibility of an aggregate exposure analysis across all of the conditions of use (Ref. 29 at p. 47).

After considering these comments, EPA finalized language in the 2017 final rule at 40 CFR 702.47 providing that the Agency would determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under each condition of use within the scope of the risk evaluation, either in a single decision document or in multiple decision documents (82 FR 33726) (Ref. 2). In the preamble to the 2017 final rule, EPA explained that the Agency would make individual risk determinations for each condition of use identified as within the scope of the risk evaluation (82 FR 33726) (Ref. 2 at p. 33744). EPA further explained in its Response to Public Comments that the sooner the Agency can determine whether a particular condition of use of a chemical substance does or does not present an unreasonable risk, the better (Ref. 29 at p. 47). With respect to comments about aggregate exposures, EPA explained that the Agency is likely to take a variety of approaches depending on the chemical substance at issue, including only making an early determination in cases where EPA has decided not to do an aggregate exposure assessment, or for those conditions of use where an aggregate exposure assessment may not be appropriate (Ref. 29 at pp. 47 through 48).

Certain petitioners challenged the 2017 final rule's condition-of-use-specific approach to risk determinations in the *Safer Chemicals* litigation before the Ninth Circuit. 943 F.3d at 412. (Ref. 6). Among other things, petitioners argued that issuing early determinations that certain conditions of use present no unreasonable risk to health or the environment would lead EPA to underestimate risk where exposure results from multiple activities involving a chemical substance, such as when the same individuals are exposed through multiple conditions of use (e.g., in the workplace and in the home). According to petitioners, such exposures may present unreasonable risk only when combined. Consistent with EPA's explanation in the Response to Public Comments document, the Agency responded that the 2017 final rule allowed EPA to issue early determinations when appropriate and that EPA would consider possible aggregate exposures in exercising such discretion, when appropriate. For example, exposure to a chemical substance may truly present no unreasonable risk under one condition of use, such as a

circumstance where inhalation is unlikely or impossible, but present an unreasonable risk under another condition of use, such as a circumstance where inhalation is prevalent. EPA also responded that the 2017 final rule also allowed EPA to issue early determinations, perform an aggregate exposure assessment for a chemical substance, and then issue one or more unreasonable risk determinations based on that aggregate assessment (Ref. 30). EPA's further noted that TSCA explicitly does not require EPA to perform an aggregate exposure assessment for every risk evaluation; rather, TSCA section 6(b)(4)(F)(ii) directs EPA to describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration (15 U.S.C. 2605(b)(4)(F)(ii)).

The Ninth Circuit held in *Safer Chemicals* that petitioners' argument was not justiciable because it was not clear that EPA would conduct risk evaluations in a manner that, under petitioners' theory, would underestimate risk from aggregate exposures. 943 F.3d at 413 (Ref. 6). Subsequent to the Ninth Circuit's decision, EPA made individual risk determinations for each condition of use evaluated in the first ten risk evaluations (i.e., the condition of use-specific approach to risk determinations). This approach resulted in a mix of findings that certain conditions of use for a chemical "present unreasonable risk" while others "do not present unreasonable risk."

In 2021, however, EPA announced a different path forward for the first ten risk evaluations (Ref. 9). In a series of *Federal Register* notices and "revised" risk determinations, EPA reopened the risk determinations for a vast majority of the first ten risk evaluations to, among other things, replace determinations for each condition of use with a single determination for each chemical substance. In doing so, EPA asserted that revising the risk evaluation to reflect a single determination of unreasonable risk did not require the Agency to perform a new risk evaluation or revise any of its underlying analyses in the risk evaluations. For each of EPA's revised risk determinations where EPA found that the chemical substance presents unreasonable risk, rather than specific conditions of use, every condition of use in the risk evaluation

proceeded to risk management, including with respect to the conditions of use that the Agency had previously found did not present unreasonable risk (e.g., Refs. 21, 31, and 32).

Although EPA indicated in its June 2021 announcement that it would make a single risk determination on a chemical when it was "clear that majority of conditions of use warrant one determination," the preamble to the 2023 proposed rule went a step further, stating that EPA now believed that the plain reading of the statute mandates a single determination for the chemical substance in every instance (88 FR 74292, October 30, 2023). The preamble also asserted that this approach was consistent with Congressional intent and would enable the Agency's risk determinations to better reflect the potential for combined exposures across multiple conditions of use. In support of this position, EPA noted that TSCA section 6(b)(4)(A) specifies that, in a risk evaluation, the Agency must determine whether "a chemical substance" presents an unreasonable risk of injury to health or the environment "under the conditions of use" (15 U.S.C. 2605(b)(4)(A)). EPA interpreted this language at the time as requiring an evaluation on the chemical substance—not each of its conditions of use—and for the evaluation to be based collectively on all of the chemical substance's "conditions of use." EPA cited other provisions of TSCA section 6 to support its new reading of the statute, including TSCA section 6(a), which requires EPA to apply risk-management requirements "to the extent necessary so that the chemical substance or mixture no longer presents such risk" (15 U.S.C. 2605(a)) and which the Agency read as suggesting that the chemical substance presents the unreasonable risk, not specific conditions of use. EPA also referenced TSCA section 6(i)(1), which provides that "a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order," and section 6(i)(2), which provides that "a final rule promulgated under subsection (a), including the associated determination . . . that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be . . . a final agency action, effective beginning

on the date of promulgation of the final rule" (15 U.S.C. 2605(i)(1) and (2)). EPA asserted that both of these provisions support the single risk determination approach because they speak to whether the chemical substance presents unreasonable risk without mentioning conditions of use.

EPA acknowledged in the 2023 proposal that there had been comments critical of this approach on the revised risk determinations that EPA issued for most of the first ten priority chemicals. The Agency noted that some commenters thought that a singular risk determination could create confusion as to whether all conditions of use or only certain conditions of use of a chemical substance pose unreasonable risk, but asserted that the potential confusion would be a communications issue that EPA would strive to improve on. The Agency also noted that other commenters expressed concern that EPA would use a single risk determination for the chemical substance to regulate in an overly broad manner, but asserted nevertheless that its statutory authority to regulate chemicals under TSCA section 6(a) 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)).

During the comment period on the 2023 proposal, some commenters supported the single risk determination approach and others opposed for similar reasons as those asserted in comments on the revised risk determinations. Industry commenters generally disagreed with EPA's reading of the statute on this point. One commenter (Ref. 33) observed that Congress found in TSCA section 2(a)(2) that "among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment" (15 U.S.C. 2601(a)(2)). According to the commenter, this language reflects a congressional recognition that particular applications of chemical substances have the potential to pose unreasonable risk, not the chemical substances themselves. Another commenter (Ref. 34) contended that the phrasing in TSCA section 6(a), along with the fact that the tools provided therein for managing unreasonable risks include both broader tools ("prohibiting or otherwise

restricting the manufacturing, processing, or distribution in commerce of such substance or mixture") and narrower ones ("prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for . . . a particular use"), means that Congress envisioned use-by-use determinations.

Industry commenters also contended that the legislative history of the 2016 TSCA amendments did not support the single risk determination approach as EPA claimed in the 2023 proposal. They cited floor statements, including by Senator Inhofe, one of the legislation's key sponsors, that "there could be circumstances where EPA determines that a chemical does not present an unreasonable risk in certain uses, but does in others" and that "[p]reemption for no significant risk determinations would apply as these determinations are made on a use-by-use basis" (Ref. 14 at p. S3521). They also cited statements by Senator Vitter, another key sponsor, stating that "[t]o be clear, every condition of use identified by the Administrator in the scope of the risk evaluation must, and will be either found to present or not present an unreasonable risk" (Ref. 14 at p. S3520).

In the 2024 Response to Comments, EPA disagreed with the industry commenters on the proper interpretation of both the language of TSCA and the legislative history of the 2016 amendments (Ref. 11). Instead, the Agency finalized the language that currently appears at 40 CFR 702.39(f)(1), which requires EPA to issue a single risk determination for the chemical substance for each risk evaluation.

2. *Risk determinations by condition of use.*

Upon further review of the 2024 final rule, EPA believes that TSCA section 6 is best read as requiring that risk determinations be made for each condition of use evaluated in the risk evaluation. There is ample support for this position in the language of TSCA section 6(b)(4)(A), which provides that EPA "shall conduct risk evaluations . . . to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially

exposed or susceptible subpopulation . . . under the conditions of use." EPA proposes that by specifying "risk evaluations" in the plural and "a chemical substance" in the singular, Congress intended to authorize the Agency to perform more than one risk evaluation, and therefore at least more than one risk determination, for the same chemical. For example, EPA could re-prioritize a chemical substance for which it already conducted a risk evaluation on, resulting in a second risk evaluation of the chemical substance. This clear authority to make multiple risk determinations is incongruent with the single risk determination approach required by the 2024 final rule.

EPA further proposes that the condition-of-use by condition-of-use approach to risk determinations is the only way to give independent meaning to the phrase "under the conditions of use," which Congress added to TSCA section 6(b) and throughout the statute in the 2016 amendments. If Congress intended to require a single risk determination for a chemical substance, there would have been no need to add the phrase at the conclusion of this provision. EPA believes this reading is also supported by TSCA section 3(4), which defines the phrase "conditions of use" as "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)). Congress used "circumstances" in the plural and included a variety of contexts that are necessarily different from one another and involve different exposures, different potentially exposed populations, and ultimately different risks.

Further, EPA proposes that the language in TSCA section 6(a) supports this reading. TSCA Section 6(a) states that "[i]f the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule . . . apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk" (15 U.S.C.

2605(b)(4)(A)). The Agency believes that this language contemplates that risk determinations will be made for each condition of use. As pointed out by several commenters on the 2023 proposal and original first ten chemical risk evaluations, it is difficult to ensure that EPA has addressed unreasonable risk in accordance with TSCA section 6(a) without first having determined whether each of the conditions of use, or any combination of particular conditions of use, presents or present an unreasonable risk to health or the environment (Ref. 11).

More generally, making a risk determination for each condition of use provides greater clarity and transparency for the regulated community and the general public. The greater clarity afforded to the regulated community by this approach fulfills the congressional policy enshrined in TSCA itself by ensuring that EPA exercises its authority to regulate unreasonable risk "in such a manner as to not impede unduly or create unnecessary economic barriers to technological innovation" (15 U.S.C. 2601(b)(3)). Indeed, Senate Report 114-67 states that the 2016 legislation was "intended to enhance confidence in the federal chemical regulatory system, provide EPA the authority necessary for efficient and effective regulation of chemical risks, and foster safety and innovation in commercial chemistry." The Senate Report goes on to explain that the legislation is "designed to ensure that the competitive advantage of the U.S. chemical industry is not eroded by regulatory mandates and that industry is subject to a more consistent set of regulations that equally protect citizens across the nation" (Ref. 35 at p. 2).

In contrast, the single risk determination approach of the 2024 final rule does not appear to align with the stated goals of the 2016 TSCA amendments. As several industry commenters on the 2023 proposal observed, the single risk determination approach is likely to result in increased confusion on the part of the regulated community, workers, consumers, and the general public (Refs. 36 and 37). EPA reiterated in the 2024 final rule that where "one or more conditions of use for the chemical present an unreasonable risk, the chemical substance itself necessarily presents an unreasonable risk" (89 FR 37028) (Ref. 1 at p. 37035). In this way, however, the single risk determination required under the 2024 final rule is uninformative for consumers

wondering whether their use of a chemical substance is safe, for workers wondering whether the exposure controls associated with their occupational exposure are sufficient to protect them (Ref. 36), or for the chemical industry wondering whether and how EPA will regulate their products (Ref. 37).

For example, the January 2025 final risk evaluation for di-isononyl phthalate (1,2-benzenedicarboxylic acid, 1,2-diisononyl ester) (DINP) found that the chemical substance presents an unreasonable risk of injury to health because 4 conditions of use (out of a total of 47) presented such unreasonable risk (Ref. 38). These 4 conditions of use represent about 3 percent of the U.S. production volume of DINP, but all production and all conditions of use of DINP were required to proceed to risk management under the single risk determination approach. The single risk determination approach obscures the fact that EPA did not find that DINP presents unreasonable risk when used under nearly all conditions of use, likely resulting in an unwarranted stigmatization of the chemical substance and unnecessary consideration at risk management.

As in the 2023 proposal, EPA acknowledged these concerns in the 2024 final rule and characterized them as a "communications issue" identified as a priority for improvement (89 FR 37028) (Ref. 1 at p. 37035). One communications improvement made by 2024 final rule is to add a requirement for EPA to identify those conditions of use that "significantly contribute" to the unreasonable risk found in the risk determination. According to the preamble, while this addition is not necessarily a perfect indicator of how EPA will ultimately regulate, it "should give industry stakeholders significant insight and more certainty" (*id.* at 37035).

Unfortunately, this addition to the 2024 final rule does not appear likely to accomplish EPA's stated objective. EPA has received consistent and widespread feedback that industry stakeholders are now confused about what it means to "significantly contribute" to the unreasonable risk presented by a chemical substance and how EPA will regulate under TSCA section 6(a) conditions of use that significantly contribute to the unreasonable risk (Ref. 39).

EPA proposes that the concept of "significantly contributes" is not based in the statutory text and not defined in any way in the 2024 final rule, meaning it both lacks a statutory basis and is vague, uninformative, and unpredictable as applied.

Rather than relying on a vague term like "significantly contributes" to identify the conditions of use of concern to EPA, and, therefore, the conditions of use that EPA is likely to regulate in a subsequent TSCA section 6(a) rule, EPA now believes that the better approach is to use the language provided by the statute and clearly state which conditions of use present an unreasonable risk to health or the environment and which conditions of use do not present such an unreasonable risk.

In addressing public comments on the confusion that could result from the single risk determination approach, EPA cautioned in the 2024 final rule against placing too much emphasis on the communicative value of the risk determination itself (89 FR 37028) (Ref. 1 at p. 37035). As described therein, the primary purpose of a risk evaluation is not to provide the public with guidance or suggested actions with respect to particular chemical uses, but rather to serve as a scientific document that informs EPA decisions on the regulatory actions needed to sufficiently address any identified unreasonable risk to health or the environment (89 FR 37028) (Ref. 1 at p. 37036). While this is true for most sections of a risk evaluation, the risk determination section is a policy section that is based on all of the inputs and assumptions of the science in the risk assessment. The risk determination section also includes explanations of scientific concepts that may not be familiar to non-scientists, such as the strength of the scientific evidence (Ref. 40 at p. 7). It is likely that many stakeholders use the risk determination section of a TSCA section 6(b) risk evaluation to better understand what conditions of use and exposures EPA evaluated, what EPA determined based on its analyses, and what conditions of use present unreasonable risk and are therefore likely to be regulated under TSCA section 6(a).

The condition of use specific risk determination approach also results in a TSCA section 9 that works as Congress intended. TSCA section 9(d) states that EPA shall coordinate with the

heads of other federal agencies "to achieve the maximum enforcement of [TSCA], while imposing the least burdens of duplicative requirements" to the regulated community. Further, TSCA section 9(a) states that if EPA makes an unreasonable risk determination and in EPA's discretion determines that the risk could be "prevented or reduced to a sufficient extent" by an action taken by another federal agency under another federal law, EPA shall submit to the other federal agency a report that includes a description of the risk and the condition(s) of use or combination of conditions of use that EPA believes presents such a risk. EPA's risk evaluations involve an analysis of multiple industries and often include findings of unreasonable risk premised on exposures to various occupational and consumer groups. In order for EPA to achieve section 9's command to avoid burdening the regulated community with "duplicative requirements," EPA must be able to efficiently consult with, and potentially refer risks to, other agencies. The condition of use specific approach will allow for this by ensuring that EPA knows precisely which agency could address the unreasonable risk presented by a specific condition of use. This is in sharp contrast to the single risk determination approach which obfuscates the exact use or uses' role in the identified unreasonable risk making it nearly impossible to effectively consult with other agencies. Additionally, because it is highly unlikely that any single agency would have the authority to address all the unreasonable risk present in a single risk determination risk evaluation, EPA would be unlikely to ever refer its risk evaluations to another agency. This would of course render section 9(a) largely superfluous; a result Congress did not intend. Thus, the condition-of-use by condition-of-use approach ensures that section 9(a) operates as envisioned by Congress.

The condition-of-use by condition-of-use approach is also supported by the text of TSCA section 18(c). TSCA section 18(c)(3)), which implements and more directly articulates the bounds of the general preemption provision in section 18(a)(1)(B), states that the scope of permanent Federal preemption of State actions is limited 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 section 6(a) or 6(i)(1)" (15 U.S.C. 2617(c)(3)). In the 2024 final rule, EPA interpreted the phrase "included in any final action" to apply 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. (89 FR 37028) (Ref. 1 at p. 37036). EPA now proposes that this reading of the phrase "included in any final action" was unnatural but necessary because when making a single risk determination on the chemical substance, no TSCA section 6(i) order would be issued for COUs that were not regulated in the TSCA section 6(a) rule. In contrast, under the condition-of-use by condition-of-use approach, a TSCA section 6(a) rule and/or a TSCA section 6(i) order would be issued, so that every COU within the scope of the risk evaluation is addressed in, that is, 'included in," one of those final agency actions and not just the risk evaluation. Although the scope of permanent preemption is the same under either approach, the condition-of-use by condition-of-use approach achieves that same scope with a more natural reading of the language "included in any final action" in TSCA section 18(c). Thus, EPA proposes that the condition-of-use by condition-of-use approach results in a more harmonious interpretation of the statute.

The preemption provisions added in the 2016 TSCA amendments are important to the regulated community. As explained in Senate Report 114-67, stakeholders were concerned that TSCA had not "fostered a robust Federal chemical regulatory system," which resulted in increased State actions on chemicals (Ref. 35 at p. 6). In the view of these stakeholders, "a proliferation of different State requirements will create confusion for the general public, and significantly increase the cost and burden of regulatory compliance for chemical manufacturers, importers and users while failing to apply any protections to more than a relatively small number of citizens" (Ref. 35 at p. 6). A commenter on the 2023 proposal stated that "[a] key motivation for TSCA reform was to create one federal standard for chemical regulation rather than a patchwork of state/local laws" (Ref. 34 at p. 8). In a floor statement, Senator Inhofe expressed

the view that "the preemption section of this bill was the most contentious issue" during the negotiations on the compromise bill that became the Lautenberg Chemical Safety for the 21st Century Act and was "the most important linchpin in the final deal" (Ref. 14 at p. S3521). Given the importance of the preemption provisions and the more natural and clearer interpretation of TSCA section 18(c) that results from the condition-of-use by condition-of-use risk determination approach, EPA now believes that it is the best interpretation of TSCA section 6(b)(4)(A).

For all of these reasons, EPA is proposing to return to making a risk determination for each of the conditions of use covered by the scope of a TSCA section 6(b) risk evaluation. Accordingly, EPA proposes to revise 40 CFR 702.39(f)(1) to read as follows: "As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use by making separate risk determinations for each condition of use within the scope of the risk evaluation, either in a single decision document or in multiple decision documents." EPA also proposes to revise 40 CFR 702.39(f)(3) because it would be superfluous, given that a risk determination would be made for each condition of use. EPA would replace the existing text in 40 CFR 702.39(f)(3) with the risk-related factors described in following paragraph. EPA emphasizes that this approach in no way precludes the Agency from determining that a condition of use, while not presenting unreasonable risk to health or the environment by itself, does present an unreasonable risk in combination with other conditions of use, assuming that the analyses in the risk evaluation support such a finding. As discussed in Unit III.C.2 of this preamble, EPA may conduct an aggregate exposure assessment where reasonably available information supports such an assessment, and an aggregate exposure assessment could support a finding that a combination of conditions of use, when considered in the aggregate, present an unreasonable risk.

The preambles of the 2017 and 2024 final rules describe how EPA may weigh a variety of factors 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 susceptible subpopulations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties (89 FR 37028) (Ref. 1); (82 FR 33726) (Ref. 2). To provide more clarity and transparency surrounding what EPA considers in determining whether unreasonable risk is presented, EPA is proposing to codify the risk-related factors EPA considers in making an unreasonable risk determination. Specifically, EPA is proposing to replace the existing text in 40 CFR 702.39(f)(3) to require that EPA consider risk-related factors in determining whether unreasonable risk is presented, including but not limited to: the severity of the hazard (e.g., the nature of the hazard and irreversibility of the hazard); exposure-related considerations (e.g., duration, intensity, and frequency of exposure); the population exposed (including any potentially exposed or susceptible subpopulations (PESS)); and the confidence in the information used to inform the hazard and exposure values, including an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization. These risk-related factors are components of the risk evaluation, as outlined in 40 CFR 702.39 (c), (d), and (e) with respect to the hazard assessment, exposure assessment, and risk characterization, respectively.

EPA requests comment on this change to the regulatory requirements for risk determinations discussed in this Unit as well as the changes regarding occupational exposure assumptions discussed in Unit III.C.1. In addition, EPA requests comments more generally on TSCA section 6(b)(4)(A) risk determinations, including whether there should be more specific requirements for how EPA is to make and document its risk determinations or whether EPA's proposal to specifically describe the factors EPA considers when making risk determinations adds sufficient clarity. Finally, while EPA is not proposing to define "unreasonable risk" in this rulemaking, because, as discussed in Unit III.B.1 of this preamble, risk determinations are case-by-case decisions, EPA requests comment on whether this rule should include a definition of the

term and, if so, how the definition should be crafted in order to preserve the unique nature of risk determinations. EPA also requests comment on whether the change to the regulatory requirements for risk determinations as well as the change s regarding occupational exposure assumptions impacts any party's reliance interests on the 2024 final rule.

C. *Risk Evaluation Considerations*

The 2024 final rule included a number of revisions to and explanations of risk evaluation considerations that EPA is now proposing to modify or clarify to be consistent with what the Agency believes to be the best reading of the statute, pursuant to the Supreme Court's decision in *Loper Bright*. EPA requests comment on all aspects of these proposed regulatory modifications and clarifications.

1. *Occupational exposure assumptions.*

EPA is proposing to amend 40 CFR 702.39(f)(2) to further clarify how the Agency will take exposure controls, such as engineering controls, administrative controls, and PPE, into account in conducting risk evaluations and making risk determinations. The revised provision would read as follows: "In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment."

In the initial risk determinations for the first ten TSCA chemical risk evaluations, EPA used professional judgement and reasonably available information to inform assumptions regarding whether workers use PPE for each condition of use, and generally assumed that workers were provided and used PPE in a manner that achieves the stated assigned protection factor (APF) for respiratory protection, or used impervious gloves for dermal protection, for many but not all conditions of use. As defined in 29 CFR 1910.134(b), APF means "the workplace level of respiratory protection that a respirator or class of respirators is expected to provide to employees when the employer implements a continuing, effective respiratory

protection program" as required by 29 CFR 1910.134. In support of this assumption, EPA relied on public comments indicating that employers, particularly in the industrial setting, implement engineering and administrative controls and provide PPE to their employees, and follow established worker protection standards (*e.g.*, OSHA regulatory requirements, recommendations from the American Conference of Governmental Industrial Hygienists (ACGIH)). Parties in litigation as well as public commenters on several TSCA risk evaluations argued that making risk determinations based on assumptions of PPE conflates the risk evaluation and risk management phases (e.g., Ref. 41). In June 2021, the Agency announced it would be revisiting the risk determinations that were based on these assumptions and noted its plans to consider information on use of PPE and other ways industry protects its workers during the risk management process (Ref. 9).

The 2024 final rule added a requirement at 40 CFR 702.39(f)(2) for EPA to consider "known and reasonably foreseen circumstances where subpopulations of workers are exposed due to the absence or ineffective use of personal protective equipment." This regulatory provision further prohibits EPA from considering "exposure reduction based on assumed use of personal protective equipment as part of the risk determination." As explained in the 2024 final rule, EPA believed that the assumed use of PPE in a risk determination could lead to an underestimation of the risk to workers for several reasons, including that not all workers are covered by OSHA standards, their employers may be out of compliance with OSHA standards, the PPE is not sufficient to address the risk from the chemical, or the PPE does not fit or function properly (89 FR 37028) (Ref. 1 at p. 37037). EPA also noted that many of OSHA's chemical-specific permissible exposure limits have not been updated in recent years.

While some commenters supported the proposed language, others objected to the perceived assumption that there was widespread noncompliance with OSHA requirements and interpreted the language to prohibit EPA from considering reasonably available information on the existing use of workplace exposure controls in the context of the risk determination (Ref. 37).

EPA is proposing to amend 40 CFR 702.39(f)(2) because it is unnecessarily confusing, it limits what EPA can consider in making an unreasonable risk determination beyond the statutory prohibition on considering non-risk factors, and it appears to be biased in favor of reasonably available information that tends to show noncompliance with mandatory and voluntary exposure control programs. TSCA section 26(k) requires EPA to consider reasonably available information in making risk evaluation decisions, including hazard and exposure information pertaining to conditions of use. EPA intends to consider the reasonably available information about personal protective equipment in each chemical risk evaluation, given this information relates to the exposures under the conditions of use and should not be cabined as information only relevant to risk management. EPA's revision would clearly comport with the requirement of TSCA to consider both reasonably available information that indicates the absence or ineffective use of worker exposure controls and information that indicates that such controls are in place and are being implemented properly. The revised 40 CFR 702.39(f)(2) would read as follows: "In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment."

2. *Aggregate exposure.*

TSCA section 6(b)(4)(F)(ii) directs EPA, when conducting a risk evaluation, to "describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration" (15 U.S.C. 2605(b)(4)(F)(ii)). While there is no mandate to conduct aggregate exposure analyses, EPA may conduct aggregate exposure analyses at its discretion. The 2017 final rule included a definition of "aggregate exposure," which the 2024 final rule amended by removing the phrase "to an individual" for the stated reason of promoting consistency with other definitions of the term and by removing the word "single" for the stated reason that TSCA allows the Agency to conduct risk evaluations on

categories of chemicals. EPA is not currently proposing to amend this definition but requests comment on the utility and clarity of the current definition.

EPA is, however, proposing to delete the language from the 2024 final rule that requires the Agency, for all risk evaluations that do not include an aggregate exposure assessment, to explain why. There are a variety of reasons why EPA would not be able to perform an aggregate exposure assessment, or why an aggregate exposure assessment would not be appropriate for one or more conditions of use. For example, while the 2024 Supplement to the Risk Evaluation for 1,4-Dioxane evaluated combined exposure and risk from multiple sources of 1,4-dioxane in surface water and combined exposure and risk across multiple facilities in proximity releasing to air, EPA did not quantitatively aggregate exposures across exposure routes and pathways due to uncertainties around the additivity of effects (Ref. 16 at sec. 1.3.1.3.3.).

The proposed removal of the language that requires EPA to explain the basis for not performing an aggregate exposure assessment, which is in addition to the statutory directive to explain the basis for performing an aggregate exposure assessment, is not meant to suggest that EPA rejects the notion of performing aggregate exposure assessments where appropriate and supported by the best available science. Rather, the burden of explaining the absence of an aggregate risk evaluation is significant and cumulative with the challenging undertaking already required to complete a risk evaluation and is not mandated by the statute. EPA is proposing to return to the language in the 2017 final rule, which tracks the statute. Accordingly, EPA proposes to delete 40 CFR 702.39(d)(8) and revise paragraph (d)(7) to include aggregate exposures.

3. *Potentially exposed or susceptible subpopulations.*

TSCA section 6(b)(4)(A) requires EPA to evaluate risk to "potentially exposed or susceptible subpopulation[s]" ("PESS") identified as relevant to the risk evaluation by the Administrator, under the conditions of use (15 U.S.C. 2605(b)(4)(A)). TSCA section 2(12) defines the term as "a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the

general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly" (15 U.S.C. 2601(12)). The 2017 final rule included this definition in 40 CFR 702.33. The 2024 final rule added the phrase "overburdened communities" to the definition's list of examples of groups of individuals that may be at greater risk. The term "overburdened communities" was not defined, although EPA stated that the term reflected its understanding and acknowledgment that a chemical substance may disproportionately expose or disproportionately impact communities already experiencing disproportionate and adverse human health or environmental burdens. EPA further explained that this "disproportionality can be as a result of greater exposure or vulnerability to environmental hazards, lack of opportunity for public participation, or other factors" (89 FR 37028) (Ref. 1 at p. 37039). The rationale given for adding this term to the regulatory definition of PESS was that specifically including overburdened communities in the regulatory definition would assist EPA and others (including the public) in understanding, and would 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 section 6(b) risk evaluation (*id.* at 37052). EPA further explained that the inclusion of overburdened communities among the potentially exposed or susceptible subpopulations considered in a risk evaluation will also enable EPA to design appropriate risk management approaches to address the unreasonable risk that the Agency may determine is presented by a chemical substance to all potentially affected people, including any unreasonable risk that is disproportionately borne by some communities.

As noted by several commenters on the 2023 proposed rule, the term "overburdened communities" as described by EPA is overbroad and could be read to include exposures and susceptibilities not tied to the specific chemical substance being evaluated (Ref. 33). Further, the "vague and expansive scope" of this term is likely to make it more difficult for EPA to meet its statutory deadlines (Ref. 33). Mindful of these concerns, EPA is proposing to remove the term "overburdened communities" from the regulatory definition of PESS at 40 CFR 702.33 to better

match the statutory text. EPA believes that the examples provided in the statute, such as children, are illustrative and do not prohibit EPA from identifying and considering additional PESS within its risk evaluations. EPA specifically requests comment on the extent to which the regulatory definition of PESS and other terms should depart from the definitions provided by TSCA.

D. *Science Policy and Scientific Standards*

1. *Peer review.*

Science is the foundation of EPA's work on TSCA risk evaluations. The quality and integrity of the science is vital to the credibility of the Agency's decisions and processes, including but not limited to the evaluation of risks from chemicals, determination of whether a condition of use of a chemical substance presents an unreasonable risk, decisions on how best to manage that risk, and ultimately the Agency's effectiveness in pursuing its mission to protect human health and the environment. One important element in ensuring that decisions are consistent with the best available science and based on the weight of scientific evidence is to have an open, transparent and independent scientific peer review process along with opportunities for public comment. 15 U.S.C. 2625(h), (i).

EPA has a long-standing history of peer review and has shown its commitment to peer review in the TSCA program. TSCA section 26(o) requires EPA to establish an advisory committee, known as the Science Advisory Committee on Chemicals (SACC), to provide independent advice and expert consultation with respect to the scientific and technical aspects of issues relating to the implementation of TSCA. EPA expects to continue to obtain scientific advice and peer review from the SACC. The 2017 final rule explicitly required peer review to be conducted on all risk evaluations, which the Agency did for each of the first ten risk evaluations (82 FR 33726) (Ref. 2 at 33743 through 33744). Reports from those peer review committees proved instructive and resulted in more robust and scientifically defensible products and improvements to EPA methods used in the risk evaluation process.

The 2024 final rule made several revisions to the regulatory provision for peer review.

First, EPA removed the reference to specific versions of guidance documents. The 2017 final rule specifically named the *EPA Peer Review Handbook 4th Edition 2015* (Ref. 42) and OMB's *Information Quality Bulletin for Peer Review* (Ref. 43). As explained in the 2023 proposal, EPA recognized that these documents may be updated and/or their names modified and sought to avoid confusion as to which guidance documents will be used. The 2024 final rule at 40 CFR 702.41 instead refers to "applicable peer review policies, procedures, guidance documents, and methods adopted by EPA and the OMB to serve as the guidance for peer review activities."

In the 2023 proposal, EPA discussed its experiences with the peer reviews conducted for the risk evaluations for the first ten TSCA risk evaluations and explained that, in the future, rather than peer reviewing an entire risk evaluation, in adhering to applicable peer review guidance, it may be appropriate for EPA to conduct peer review on only portions or sections that constitute unreviewed influential information (88 FR 74292, October 30, 2023) (Ref. 10 at p 74307). EPA also explained that it expects that a TSCA risk evaluation may use peer reviewed products (e.g., risk assessments, hazard assessments, models), or portions thereof, conducted by another EPA office or other authoritative body (e.g., state, national, or international programs) that adhered to the best available science and weight of scientific evidence standards. To clarify, EPA proposed revisions to 40 CFR 702.41 that would incorporate EPA's expectation that peer review activities could be conducted on risk evaluations "or portions thereof."

As stated in the 2024 final rule, EPA received many comments on these proposed changes, most of which did not support the new approach to peer review. Commenters thought that the removal of the references to specific guidance documents could potentially result in a lack of clarity as to which policies, procedures, guidance documents, and methods were applicable (Ref. 37). Commenters also thought that the addition of the phrase "or portions thereof" and the framing of "EPA expects" would give EPA too much flexibility, resulting in limited, less transparent peer reviews, or potentially none at all. In response to these comments, the 2024 final rule removed the reference to specific guidance documents as proposed, and

included the "EPA expects" framing, but did not add the phrase "or portions thereof" (89 FR 37028) (Ref. 1 at 37041 through 37042).

EPA is not proposing to restore the 2017 final rule provisions for peer review that referenced specific versions of guidance documents or explicitly required peer review to be conducted on all risk evaluations (i.e., did not include the "EPA expects" framing that allows EPA to consider the complexity, novelty, and any prior peer review to determine the appropriate approach to and scope of peer review to apply). However, EPA is requesting comment on whether the 2017 language describing peer review provisions should be restored, or whether other amendments to the peer review provision should be considered. More generally, EPA requests comment on how to ensure transparency and accountability in the peer review of risk evaluations, consistent with language in the *EPA Peer Review Handbook 4th Edition 2015* (Ref. 42), OMB's *Information Quality Bulletin for Peer Review* (Ref. 43), OMB's *Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by Federal Agencies* (Ref. 44), and OMB's *Memorandum M-19-15, Memorandum for the Heads of Executive Departments and Agencies: Improving Implementation of the Information Quality Act.*(Ref. 45).

2. *Definitions.*

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. 15 U.S.C. 2625(h) and (i). 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." 15 U.S.C. 2625(h). The statute then lists considerations: (1) The extent to which the scientific information, technical procedures, measures, methods, protocols, methodologies, or models employed to generate the information are reasonable for and consistent with the intended use of

the information; (2) The extent to which the information is relevant for the Administrator's use in making a decision about a chemical substance or mixture; (3) The degree of clarity and completeness with which the data, assumptions, methods, quality assurance, and analyses employed to generate the information are documented; (4) The extent to which the variability and uncertainty in the information, or in the procedures, measures, methods, protocols, methodologies, or models, are evaluated and characterized; and (5) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models. *Id.* Section 26(i) states "the Administrator shall make decisions under sections 4, 5, and 6 based on the weight of scientific evidence." 15 U.S.C. 2625(i). 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.

During the development of the 2017 proposed rule, EPA received input from stakeholders about the codification of definitions for these terms (Refs. 2 and 29). Some noted that it is imperative that the Agency have specific criteria which would allow for consistency and transparency for how EPA will implement science. Others contended that since interested persons may submit risk assessments to the Agency for consideration (under TSCA section 26(l)(5)), it is necessary for the Agency to provide a standard and expectation. 15 U.S.C. 2625(l)(5). Many noted that there are a number of ways the Agency could and has defined these terms across other statutory obligations and suggested this could be both a reason to codify TSCA-specific definitions, or to not codify them to avoid future limitations in implementation approaches. Others thought that codification of specific process definitions would limit the Agency's ability to adapt to the changing science of risk evaluation, as well as the science that informs risk evaluation.

The 2017 proposed rule did not include definitions for either of these terms (82 FR 7562) (Ref. 27 at p. 7572), citing the need to remain flexible to changing science and approaches. Ultimately, EPA chose to codify definitions for both of these terms in the final rule, explaining

that this would instill confidence, increase transparency, predictability, and provide the public with assurance that EPA will adhere to the requirements of the statute (Ref. 29 at p. 11). The definition of "best available science" incorporated much of the direction from TSCA section 26(h). In the response to comments document, EPA further explained that the definitions that EPA had chosen to codify, particularly for best available science and weight of scientific evidence were not overly prescriptive, but instead captured universal principles, which EPA did not think would restrict flexibility or scientific advancement.

In the 2024 final rule EPA removed the definitions of best available science and weight of the scientific evidence, explaining that they were unnecessary and could act to limit the Agency's flexibility and, therefore, its ability to meeting the science standards of TSCA section 26. EPA discussed in detail the existing requirements for using the best available science in TSCA section 6(b) risk evaluations, including TSCA itself, as well as other guidance documents such as OMB's Information Quality Guidelines (Ref. 44). Similarly, EPA described four guidance documents that it would look to in implementing the TSCA section 26(i) directive to make decisions based on the weight of the scientific evidence (89 FR 37028) (Ref. 1 at 37044). EPA further explained that the 2017 final rule's definition of weight of the scientific evidence appeared to conflate two ideas, weight of the scientific evidence and systematic review. In the 2024 final rule EPA also described the expected application of systematic review methods for identifying and assessing reasonably available information to uphold TSCA's scientific standards for "best available science" and "weight of scientific evidence," including that the Agency may consider existing assessments conducted by EPA or other federal, state, or international authoritative bodies, determine 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. More information on the rationale for removing these definitions and not promulgating alternatives, or a definition of systematic review, can be found in the 2024 final rule (*Id.* at 37042 through 37045).

EPA is not proposing to restore the 2017 final rule definition for best available science because much of the 2017 definition is incorporated into 40 CFR 702.37(a). However, to enhance transparency in its approach to risk evaluations, EPA is proposing to incorporate the definition of "weight of scientific evidence" from section 2(e) of Executive Order 14303 (Ref. 4). EPA believes that this definition appropriately captures the intention behind TSCA sections 6(b)(4)(F)(v) and 26(i). The proposed definition is "an approach to scientific evaluation in which each piece of relevant information is considered based on its quality and relevance, and then transparently integrated with other relevant information to inform the scientific evaluation prior to making a judgment about the scientific evaluation. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, and transparency and reliability of data." To meet the law's requirement to base decisions in TSCA risk evaluations on the "weight of the scientific evidence," EPA expects to continue to rely on established and peer reviewed Agency guidance documents or any successor documents to guide weight of scientific evidence analysis under TSCA and to provide a summary weight of scientific evidence narrative or characterization, as described in the 2024 final rule (89 FR 37028) (Ref. 1 at 37044). EPA's guidance documents all similarly describe the weight of scientific evidence 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. EPA is requesting comment on all aspects of the proposed definition of "weight of scientific evidence" and related terms, including the specific terms within the definition and their meaning, and whether the consideration of strengths, limitations, and uncertainties associated with integrating lines of relevant information, is appropriately captured. Additionally, the Agency seeks comment on whether the 2017 definition for "best available science" should be restored, whether other definitions for these terms should be considered, and whether EPA should promulgate a definition of systematic review. EPA is also requesting comment on how the Agency can apply

systematic review methods for TSCA risk evaluations that leverage consideration of systematic review approaches and risk assessments from other EPA offices and authoritative bodies. More generally, EPA requests comment on how to ensure transparency and accountability in conducting risk evaluations, including making risk determinations.

3. *Occupational exposure value.*

The 2024 final rule preamble contained a discussion of how Existing Chemical Exposure Limits (ECELs) were calculated for the first ten priority chemicals, and how some ECELs were issued at a different time than the risk evaluation on which they were based (89 FR 37028) (Ref. 1 at 37040). EPA also explained that these early ECELs were risk-based occupational exposure values, and did not take non-risk factors into account. Using the same terminology, EPA incorporated these ECELs into the subsequent TSCA section 6(a) risk management rules (e.g., Ref. 46). However, EPA soon realized that using the same term, ECEL, for both a risk-based occupational exposure value and an enforceable regulatory exposure limit applied in a risk management rule, where costs and other non-risk factors may be considered, was confusing. As a result, EPA stopped referring to the risk-based occupational exposure value as an ECEL.

In the 2023 proposed rule EPA requested comment on how the Agency could improve the transparency of risk-based occupational exposure values derived from the risk evaluation process (88 FR 74292, October 30, 2023) (Ref. 10). Commenters generally expressed a preference for more opportunity for public review and scientific input on how the values are derived, and for a more formalized approach to developing corresponding regulatory limits (89 FR 37028, May 30, 2024) (Ref. 1 at p 37040). In response to these comments, EPA began issuing draft risk-based occupational exposure values in, or concurrently with, draft risk evaluations (Refs. 47 and 48). The 2024 final rule also provides, at 40 CFR 702.49(h), that where unreasonable risk to workers is identified via inhalation, EPA will make available a calculated risk-based occupational exposure value.

EPA is not specifically proposing changes to 40 CFR 702.49 at this time. However, EPA

is requesting comment on whether EPA should establish occupational exposure values, and, if so, whether EPA should do so as part of the risk evaluation for a chemical substance, or in the subsequent risk management rule, or both. If both, EPA requests comments on what considerations EPA should be taking into account in moving from the value established as part of the risk evaluation to the value established during risk management.

E. *Process for EPA Revisions to Scope or Risk Evaluation Documents*

The 2024 final rule established new procedures and criteria for whether and how EPA would endeavor to revise or supplement final scope documents, and draft or final risk evaluations. The 2017 final rule did not provide for any special procedures or criteria for these actions. Under the procedures in the 2024 final rule, changes to a draft scope document or a draft risk evaluation will be described in the final scope document or final risk evaluation. Changes to the scope of a risk evaluation after the final scope document has been published will either be described in the draft risk evaluation or separately in a notice of availability published before the draft risk evaluation. So far, none of this represents a departure from what EPA's practice has been since implementation of the 2016 TSCA amendments began. For example, information about an additional condition of use for 1,4-dioxane was brought to EPA's attention after the scope of the risk evaluation was published, and the expanded scope is discussed in the draft risk evaluation (Ref. 49 at sec. 2.4.1.) The 2024 final rule departed from established risk evaluation practice in promulgating new criteria and procedures for revising final risk evaluations. 40 CFR 702.43(g)(3) states that "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 . . . ." Should EPA determine to revise or supplement a final risk evaluation, 40 CFR 702.43(g)(4) requires EPA to follow the procedures set forth in the section, including publication of draft and final risk evaluations and public comment periods.

One rationale given for the new procedures and criteria is to provide greater certainty and transparency for stakeholders. However, as explained in the 2023 proposal, given the tens of thousands of existing chemical substances in commerce and EPA's responsibility to assess and manage risks from those chemicals through a statutory deadline-driven pipeline of prioritization, risk evaluation and risk management activities, the new procedures and criteria for revising final risk evaluations are intended to ensure that the Agency continues to make forward progress on existing chemicals as Congress intended, and does not drain already limited resources and divert attention from other chemicals actively in the prioritization, risk evaluation or risk management phases by continuously revisiting final risk evaluations (88 FR 74292, October 30, 2023) (Ref. 10 at p. 74311). In the 2023 proposal, EPA further explained that re-prioritizing a chemical substance will provide the public with ample notice and opportunity to engage, provide anticipatable milestones and process, and better position the Agency to maintain a manageable workload (88 FR 74292, October 30, 2023) (Ref. 10 at p. 74312). Nevertheless, EPA recognized in the 2023 proposal that there may be instances where revisions to a final risk evaluation outside of re-prioritization of a chemical are in the interest of protecting human health and the environment.

While EPA appreciates the magnitude of the task assigned by Congress in section 6 of TSCA, EPA maintains its authority to revise final risk evaluations without going back through the prioritization process, and not just because the revision is needed to protect human health or the environment. Stakeholders, including States, the regulated community, workers, consumers, and the general public, must have confidence in EPA's risk evaluations under TSCA section 6, including that they represent the best available science and are based on the weight of the scientific evidence. To the extent that it becomes apparent that a risk evaluation does not meet the statutory science standards under TSCA section 26(h) and (i), EPA must be able to fix it. The 2023 proposed rule provides an example of just such an instance, a scientific error that meaningfully impacts the risk evaluation or the Agency's ability to appropriately address risks

through rulemaking (88 FR 74292, October 30, 2023) (Ref. 10 at p. 74312). The 2023 proposed rule language implies that the only time EPA should revise a risk evaluation that includes such a scientific error without going back through prioritization is when the revision is needed to protect human health or the environment. However, a scientific error could also result in a determination that a condition of use presents an unreasonable risk, when, in fact, it does not. Promulgating a TSCA section 6(a) risk management rule based on that faulty risk determination could entail burdensome requirements for industry without the anticipated benefits and potentially impair the competitiveness of the American manufacturing and industrial sectors or negatively impact the health and safety of workers.

In conducting risk evaluations, or revising or supplementing final risk evaluations, EPA is bound by the procedural requirements of TSCA section 6 and the implementing regulations at 40 CFR part 702. As described in this Unit, EPA believes that the limitation in 40 CFR 702.43(g)(3) on revising or supplementing final risk evaluations, as promulgated in the 2024 final rule, is not consistent with EPA's obligations under TSCA section 6 to assess and manage risks within the statutory deadlines. For this reason, EPA is proposing to remove 40 CFR 702.43(g)(3) in its entirety, and to amend subparagraph (g)(3) to read as follows: "*Final risk evaluations.* When EPA supplements or revises, in whole or in part, a final risk evaluation, EPA will follow the 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." EPA requests comment on this change, and also on whether there are circumstances that would allow for the correction of a scientific error or to make other revisions without reopening the risk evaluation or going back to the draft risk evaluation stage. EPA requests comment on whether there should be criteria for when a final risk evaluation should be revised, including circumstances where EPA becomes aware of information that was developed after the risk evaluation was finalized, as well as comment on circumstances that would not warrant reopening the risk evaluation or going back to the draft risk evaluation

stage.

EPA requests comment on two alternatives to the above approach. First, the Agency could remove all regulatory text related to revising or supplementing existing risk evaluations and not replace the current language with an analogous provision. Under this approach, EPA's procedural framework rule would arguably satisfy the statutory requirement to "establish, by rule, a process to conduct risk evaluations" (15 U.S.C. 2605(b)(4)(C)) by setting out the process for a risk evaluation while remaining silent on whether and how to revise or supplement an evaluation. That would leave the Agency's assertion of authority to revise and supplement an evaluation to particular cases. While this approach would increase flexibility, EPA acknowledges that the absence of such language could undermine interests in certainty and predictability.

Second, the Agency could retain the current regulatory language added in the 2024 final rule, except for the provision allowing EPA to supplement or revise on an ad hoc basis in the interest of public health or the environment. This approach would address the Agency's concerns with the one-sided nature of the current regulatory allowance for supplementation and revision while retaining the position that EPA generally will not revise or supplement a risk evaluation without re-prioritizing the chemical substance for a new risk evaluation. While this approach would increase certainty and predictability, and helps to ensure that the Agency proceeds to evaluate listed chemicals promptly rather than revisiting already evaluated chemicals, EPA acknowledges such a requirement would make it more difficult to update evaluations and determinations for evaluated chemicals and conditions of use and reduce the Agency's flexibility. EPA seeks comment on both alternative approaches and any other approaches that commenters believe the Agency should take to revisions and supplements in any final rule.

F. *Requirements for Manufacturer-Requested Risk Evaluations*

The 2024 final rule incorporated a number of changes to the provisions for manufacturer-requested risk evaluations (MRREs). TSCA section 6(b)(4)(C)(ii) allows a manufacturer or group of manufacturers to request that the Agency conduct a risk evaluation of a chemical

substance (or category of substances) that they manufacture. TSCA section 6(b)(4)(C)(ii) directs EPA to establish the "form . . . manner and . . . criteria" for such requests by rule, which the Agency finalized in 2017.

Many of the changes in the 2024 final rule were understandable process changes based on EPA's experience in handling such requests and on implementing TSCA section 6(b) in general. However, the 2024 final rule includes new requirements for requesting manufacturers, including requirements to provide all information "known to or reasonably ascertainable by" the requesting manufacturer regarding a chemical substance's conditions of use, hazards, and exposures. 40 CFR 702.43(a)(8) defines the phrase "known to or reasonably ascertainable by" as including all information in the requesting manufacturer's possession or control, as well as information obtained through a thorough search of publicly available information, a reasonable inquiry within the requester's entire organization, and a reasonable inquiry outside of the requester's organization, including suppliers and downstream users. Further, 40 CFR 702.43(e)(7) provides that, should EPA determine that additional information is needed to carry out the risk evaluation, the requester will provide the requested information, withdraw the risk evaluation request, or request that EPA use its authorities under TSCA sections 4, 8, or 11 to obtain the information because the information is not reasonably ascertainable to the requester.

As explained in the 2024 final rule, the process established for MRREs in 2017 was challenging for EPA in a number of ways. The 2017 final rule allowed requests to contain information relevant only to conditions of use of the chemical of interest to the requesting manufacturer and also gave EPA a relatively short period of time in which to grant or deny the request. Once EPA granted the request, the statutory three-year clock for completing the risk evaluation began. EPA further explained that the process effectively left the Agency with the heavy burden of identifying the remaining conditions of use, reviewing information that came in with the request, obtaining and reviewing additional available literature, and determining any missing information or data needs – all within a matter of months. The 2024 final rule asserted

that, in addition to needing more information in incoming requests, and additional time to properly review them and determine any additional information needs prior to initiating the evaluation, EPA also needed some flexibility in the process to pursue data collection or development during the risk evaluation. In support, EPA pointed to the process and timeframes that precede EPA-initiated risk evaluations in prioritization, which provides a significant amount of time to review and analyze available information, identify data gaps and needs, and pursue various data gathering strategies, all before initiating the risk evaluation and the associated deadlines.

While these challenges are evident with the MRREs that EPA has received, the 2024 final rule's solution requires manufacturers to take on the obligation to identify all of the conditions of use for the chemical substance and to supply all of the information that would be needed for EPA to perform the risk evaluation, including information for conditions of use that they, their suppliers, and their customers were not engaged in. The responsibility for determining the conditions of use of a chemical substance and, thereby, the scope of the TSCA section 6(b) risk evaluation, rests with EPA, and forcing manufacturers to undertake some of the same tasks that EPA performs with regard to risk evaluations that arise from the prioritization process is inefficient.

EPA is therefore proposing to revise 40 CFR 702.45 to generally scale back the information collection obligations that the 2024 final rule imposed on requesting manufacturers, particularly with respect to conditions of use that neither the manufacturers nor their customers are engaged in. EPA would delete the statement at 702.45(a)(3) that manufacturers are obligated to provide EPA with the information needed to carry out the risk evaluation, as well as the statement at 702.45(a)(5) that manufacturers are obligated to develop, at any time during the risk evaluation process, information that EPA determines is necessary to complete the risk evaluation. TSCA provides EPA with various information collection authorities, including section 4(a)(2) that specifically allows EPA to require, by rule, order, or consent agreement, the

development of new information needed to support a TSCA section 6(b) risk evaluation. This requirement may be directed at any manufacturers and processors, including those manufacturing or processing a chemical substance for a different purpose than the requesting manufacturer.

For the same reasons, EPA is proposing to revise 40 CFR 702.45(a)(8) to read as follows: "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." In EPA's view, this is a reasonable measure of the information that requesting manufacturers ought to be able to provide without significant additional effort. This definition also comports with how the term is used in other TSCA regulations, including 40 CFR 704.3. EPA requests comment on whether this or another such standard is appropriate for manufacturer requests.

EPA is also proposing to modify the content requirements for manufacturer requests to make it clear that requesters are only obligated to submit information on the conditions of use that they have identified in their request. So, for example, EPA would revise 702.45(c)(4) to read as follows: "A description of the circumstances for which the manufacturer is requesting that EPA conduct a risk evaluation, all information known to or reasonably ascertainable by the requesting manufacturer that supports the identification of the requested circumstances, and a rationale for why the requested circumstances constitute conditions of use under 702.33."

EPA is similarly proposing to revise 40 CFR 702.45(e) to limit manufacturer information obligations to information about the identified conditions of use, and to clarify the decisions EPA will make regarding request completeness and the result of the request. In general, EPA will grant requests that are complete and that provide sufficient information to permit EPA to complete a risk evaluation on the identified conditions of use. To the extent that EPA lacks other information needed to perform a comprehensive risk evaluation on the chemical substance, such as information about other conditions of use, revised paragraph (e)(7) would require EPA to

develop a strategy to obtain the information and would permit EPA to delay initiation of the risk evaluation on the chemical substance for up to one year in order to obtain the information using available TSCA authorities.

Finally, EPA is revising paragraphs (g) and (k) to clarify that manufacturer requests that are withdrawn before the request is granted do not incur fees. EPA requests comment on all aspects of the changes being proposed to the requirements for manufacturer-requested risk evaluations.

G. Severability

EPA intends that the provisions of this proposed rulemaking would, if finalized, be severable from one another. In the event that any individual provision or part of this rulemaking is invalidated, EPA intends that this would not render the entire rulemaking invalid, and that any individual provisions that are finalized would continue to be followed.

IV. Requests for Comment

EPA requests comment on all aspects of the proposal. Additionally, within this proposal, the Agency is soliciting feedback from the public on specific issues throughout this proposed rule. For ease of review, this unit summarizes those specific requests for comment, with numbering provided to help simplify referencing.

1. In Unit I.C., EPA requests comment on how the requirements of this rule, when finalized, would apply to risk evaluations initiated prior the effective date of the final rule, and whether these requirements shall not apply retroactively to risk evaluations already finalized.

2. In Unit I.E, EPA requests specific comment on the burden estimate and assumptions associated with the calculation associated with the burden (*e.g.*, number of manufacturer requests for risk evaluations that EPA expects). More generally, EPA requests comment on whether and how the proposed rule would reduce burdens, and welcomes detailed information, examples, and data addressing the impacts of the rule.

3. In Unit III.A.2, EPA requests comment on the proposed amendments to 40 CFR

702.37(a)(3) and (4), including whether the revisions are sufficiently clear as to EPA's intent regarding appropriately scoped, fit-for-purpose risk evaluations under TSCA section 6(b). EPA is also interested in comments on how to address conditions of use that are identified after the conclusion of a risk evaluation on a chemical substance.

4. In Unit III.A.3, EPA requests comment on whether the Agency should include regulatory text that specifies that EPA has discretion to exclude conditions of use as well as exposure pathways and routes. Further, EPA requests comment on specific instances where EPA should exercise its authority to exclude conditions of use and exposure pathways and routes. EPA also requests comment on whether to add regulatory text that states that EPA can coordinate actions with other federal laws administered by EPA to ensure that chemical risks "could be eliminated or reduced to a sufficient extent" by other EPA actions, pursuant to TSCA section 9(b). Finally, EPA welcomes suggested regulatory text that could be considered.

5. In Unit III.B.2, EPA requests comment on the change to the regulatory requirements for risk determinations discussed in Unit III.B.2., as well as the changes regarding occupational exposure assumptions discussed in Unit III.C.1. In addition, EPA requests comments more generally on TSCA section 6(b)(4)(A) risk determinations, including whether there should be more specific requirements for how EPA is to make and document its risk determinations.

6. In Unit III.C, EPA requests comment on all aspects of the proposed regulatory modifications and clarifications to provisions from the 2024 final rule related to risk evaluation.

7. In Unit III.C.2 EPA requests comment on the clarity and utility of the current definition of "aggregate exposure."

8. In Unit III.C.3, EPA requests comment on the extent to which the regulatory definition of PESS and other terms should depart from the definitions provided by TSCA.

9. In Unit III.D.1, EPA requests comment on whether the 2017 language describing peer review provisions should be restored, or whether other amendments to peer review should be considered. More generally, EPA requests comment on how to ensure transparency and

accountability in the peer review of risk evaluations.

10. In Unit III.D.2, EPA is requesting comment on all aspects of the proposed definition of "weight of scientific evidence" and related terms, including whether the 2017 definition for "best available science" should be restored, whether other definitions for these terms should be considered, and whether EPA should promulgate a definition of systematic review. More generally, EPA requests comment on how to ensure transparency and accountability in conducting risk evaluations, including making of risk determinations.

11. In Unit III.D.3, EPA requests comment on whether EPA should establish occupational exposure values, and, if so, whether EPA should do so as part of the risk evaluation for a chemical substance, or in the subsequent risk management rule, or both. If both, EPA requests comments on what considerations should be taken into account in moving from the value established as part of the risk evaluation to the value established during risk management.

12. In Unit III.E, EPA requests comment on the proposed changes to 40 CFR 702.43(g), the two alternatives EPA is considering in lieu of the proposed changes to 40 CFR 702.43(g), and also on whether there are circumstances that would allow for the correction of a scientific error without reopening the risk evaluation or going back to the draft risk evaluation stage.

13. In Unit III.F, EPA requests comment on all aspects of the changes being proposed to the requirements for manufacturer-requested risk evaluations, including whether the proposed revision to 40 CFR 702.45(a)(8) regarding information known to, or reasonably ascertainable by the manufacturer outlined in Unit III.F, or another such standard, is appropriate for manufacturer requests.

V. References

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VI. Statutory and Executive Order Reviews

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

A. *Executive Orders 12866: Regulatory Planning and Review and 13563: Improving Regulation and Regulatory Review*

This action is a significant regulatory action that was submitted to OMB for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 11, 2011). Any changes made in response to Executive Order 12866 review have been documented in the docket. EPA prepared an analysis of the potential costs and burdens associated with this action. This analysis can be found in Unit VI.C.

B. *Executive Order 14192: Unleashing Prosperity Through Deregulation*

This action is expected to be an Executive Order 14192 deregulatory action. Details on the estimated direct cost savings of this proposed rule can be found in Unit I.E and in the Information Collection Request (ICR) document entitled “Procedures for Requesting a Chemical Risk Evaluation under TSCA (Proposed Rule)” (Ref. 5). Additionally, although EPA's determinations as to whether a chemical presents unreasonable risk under its conditions of use are necessarily made without consideration of cost or other non-risk factors through the course of

a TSCA risk evaluation, by proposing to amend the procedural rule to reassert EPA's discretion (*e.g.*, to determine the scope of the risk evaluation and to make a risk determination for each condition of use of a chemical substance instead for the chemical substance as a whole), the Agency anticipates that it could also be responsive to public comments that have suggested that unreasonable risk determinations formulated under the 2024 final rule would necessarily result in regulatory actions that would be overbroad and overly burdensome compared to potential actions in response to unreasonable risk determinations that are tailored to individual conditions of use.

C. *Paperwork Reduction Act (PRA)*

The information collection activities in this proposed rule have been submitted for approval to OMB under the PRA, 44 U.S.C. 3501 *et seq*. EPA has prepared a new rule-related Information Collection Request (ICR) document entitled "Procedures for Requesting a Chemical Risk Evaluation under TSCA (Proposed Rule)" and is identified by EPA ICR No. 2781.03, to replace an existing approved ICR. You can find a copy of the new ICR document (Ref. 5) 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. 2781.02 and OMB Control No. 2070-0231) (Ref. 50). The proposed rule replacement ICR addresses the information collection requirements contained in the current regulations as well as in the amendments identified in this proposed rule. As addressed in the currently approved ICR and pursuant 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 proposed amendments to information requirements for manufacturer-requested risk evaluations, including proposed amendments to information requirements addressing joint submissions, the scope of the requested risk evaluation, and the information to be provided in support of the requested risk evaluation, and fee payment. Please see Unit III.F. for additional information about these proposed amendments.

This ICR revision addresses adjustments to the estimated time for activities and wage rates related to the current regulatory requirements as approved under OMB Control No. 2070-0202. In addition, the ICR revision 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. 2070-0231 is 166 hours. The total estimated annual respondent burden being proposed in the replacement ICR is 166 hours, a net decrease of 0 hours. 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 (per year).

Frequency of response: On occasion.

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

Total estimated cost: $91,831 (per year), includes $0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a

collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA's regulations in 40 CFR are listed in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this rule. EPA will respond to any ICR-related comments in the final rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs using the interface at *https://www.reginfo.gov/public/do/PRAMain*. Find this particular ICR by selecting "Currently under Review - Open for Public Comments" or by using the search function. OMB must receive comments no later than [**INSERT DATE 30 DAYS AFTER PUBLICATION IN THE *FEDERAL REGISTER***].

D. *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. In making this determination, EPA concludes that the impact of concern for this action is any significant adverse economic impact on small entities and that the Agency is certifying that this action will not have a significant economic impact on a substantial number of small entities because the action can relieve regulatory burden on the small entities subject to the rule and the number of small entities likely to be affected may be approximately 1 or less a year as estimated in Unit VI.C of this preamble. As described in Units I.E and VI.B, this proposal would reduce the amount of information a manufacturer would have to provide with a voluntary request for a risk evaluation. Details of this analysis are presented in the rule-related ICR (Ref. 5). We have therefore concluded that this action can relieve regulatory burden for all directly regulated small entities.

E. *Unfunded Mandates Reform Act (UMRA)*

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any state, local or tribal governments. The costs involved in this action

are imposed only on the private sector entities (manufacturers) that may voluntarily elect to submit a request for a risk evaluation as they would be required to comply with the proposed requirements for such requests. Such costs are estimated not to exceed $183 million in 2023$ ($100 million in 1995$ adjusted for inflation using the GDP implicit price deflator) or more in any one year.

F. *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.

G. *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.

H. *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 regulatory actions considered significant under section 3(f)(1) of Executive Order 12866 and that concern environmental health or safety risks that EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of Executive Order 13045. Since this action is not a "covered regulatory action" because it is neither a significant regulatory action under section 3(f)(1) of Executive Order 12866 nor an action that concerns an environmental health risk or safety risk, Executive Order 13045 does not apply. Since this action does not concern human health risks, EPA's Policy on Children's Health

also does not apply. This procedural rule would address how EPA evaluates the risks of existing chemicals under TSCA, including potential risks to children and other PESS. EPA must initiate a rulemaking to address the unreasonable risk to human health or the environment that the Agency may determine are presented by a chemical substance as set forth in a TSCA risk evaluation. Although this procedural rule itself would not directly affect the level of protection provided to human health or the environment, EPA expects that a rulemaking under TSCA section 6(a) could qualify as a covered regulatory action under EO 13045 and therefore could be subject to EPA's Policy on Children's Health.

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

This action is not a "significant energy action" as defined in 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. This procedural rule would address how EPA evaluates the risks of existing chemicals under TSCA and information requirements for manufacturers who would submit a request that EPA conduct a risk evaluation.

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

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

List of Subjects in 40 CFR Part 702

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

Lee Zeldin

Administrator.

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

PART 702—GENERAL PRACTICES AND PROCEDURES

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

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

Subpart B — Procedures for Chemical Substance Risk Evaluations

2. Amend § 702.31 by revising paragraph (c) to read as follows.

§ 702.31 General provisions.

*****

(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 [DATE 30 DAYS AFTER THE DATE OF PUBLICATION OF THE FINAL RULE IN THE *FEDERAL REGISTER*]. For risk evaluations initiated prior to this date, but not yet finalized, EPA will seek to apply the requirements in this subpart to the extent practicable. These requirements shall not apply retroactively to risk evaluations already finalized.

*****

3. Amend § 702.33 by revising the definition of "Potentially exposed or susceptible sub-population" and adding a definition of "Weight of the scientific evidence" to read as follows*:*

§ 702.33 Definitions.

*****

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, or the elderly.

***

Weight of scientific evidence means an approach to scientific evaluation in which each piece of relevant information is considered based on its quality and relevance, and then transparently integrated with other relevant information to inform the scientific evaluation prior to making a judgment about the scientific evaluation. Quality and relevance determinations, at a minimum, should include consideration of study design, fitness for purpose, replicability, peer review, and transparency and reliability of data.

4. Amend § 702.37 by revising and republishing paragraphs (a)(3) and (4) to read as follows:

§ 702.37 Evaluation requirements.

*****

(a) *Considerations.*

***

(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 technically sound determinations as to whether the chemical substance presents an unreasonable risk of injury to health or the environment under each of the conditions of use, based on the weight of the scientific evidence. 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 conditions of use in any risk evaluation will vary as necessary to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under that condition of use.

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

*****

5. Amend § 702.39 by removing paragraphs (d)(8) and (9), and revising paragraphs (d)(7) and (f) to read as follows:

§ 702.39 Components of risk evaluation.

*****

(d) *Exposure assessment.*

***

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

*****

(f) *Risk determination.*

(1) As part of the risk evaluation, EPA will determine whether the chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use by making separate risk determinations for each condition of use within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

(2) In determining whether unreasonable risk is presented, EPA's consideration of occupational exposure scenarios will take into account reasonably available information on the implementation and use of occupational exposure control measures such as engineering and administrative controls and personal protective equipment.

(3) In determining whether unreasonable risk is presented, EPA will consider the following risk-related factors included in the risk evaluation, as outlined in 40 CFR 702.39 (c), (d), and (e), and any other risk-related factors that are relevant:

(i) The severity of the hazard (e.g., the nature of the hazard and irreversibility of the hazard);

(ii) Exposure-related considerations (e.g., duration, intensity, and frequency of exposure);

(iii) The population exposed (including any potentially exposed or susceptible subpopulations (PESS)); and

(iv) The confidence in the information used to inform the hazard and exposure values, including an evaluation of the strengths, limitations, and uncertainties associated with the information used to inform the risk estimate and the risk characterization.

6. Amend § 702.43 by revising and republishing paragraphs (e), (f), and (g) to read as follows:

§ 702.43 Risk evaluation actions and timeframes.

*****

(e) *Final determination of unreasonable risk.* Upon a determination by EPA pursuant to § 702.39(f) that one or more conditions of use of a chemical substance present an unreasonable risk of injury to health or the environment, EPA will initiate action as required pursuant to 15 U.S.C. 2065(a).

(f) *Final determination of no unreasonable risk.* A determination by EPA pursuant to § 702.39(f) that a condition of use of a 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 evaluations*.

Where EPA supplements or revises, in whole or in part, a final risk evaluation, EPA will follow the 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.

7. Amend § 702.45 by revising and republishing to read as follows:

§ 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) 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.

(4) 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).

(5) 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.

(6) 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.

(7) 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 this section applies 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 for which the manufacturer is requesting that EPA conduct a risk evaluation, all information known to or reasonably ascertainable by the requesting manufacturer that supports the identification of the requested circumstances, and a rationale for why the requested circumstances constitute conditions of use under 702.33.

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

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

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

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

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

(v) 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 conditions of use identified by the manufacturer.

(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 relevant information.

(4) *Secondary review for sufficiency.*

(i) Within 90 days following the end of the comment period in paragraph (e)(3) of this section, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the criteria and requirements of 40 CFR 702.37.

(ii) EPA will determine whether the circumstances identified in the request constitute conditions of use under 40 CFR 702.33, and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also determine whether any additional conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance.

(iii) 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 on the conditions of use identified by the requesting manufacturer(s).

(5) *EPA's decision.*

(i) Where EPA determines a request to be complete and sufficiently supported in accordance with paragraphs (e)(2) and (4) of this section, that the circumstances identified in the request constitute conditions of use that warrant inclusion in a risk evaluation for the chemical substance, and that EPA believes that it has all of the information needed to complete a risk

evaluation on the conditions of use identified by the manufacturer(s), EPA will grant the request, subject to the percentage limitations in TSCA section 6(b)(4)(E)(i)(II).

(ii) Where EPA determines that the requesting manufacturer(s) did not provide sufficient information to complete the risk evaluation on the identified conditions of use, or where the circumstances identified in the request either do not constitute conditions of use or do not warrant inclusion in a risk evaluation for the chemical substance, EPA will deny the request.

(iii) Within 90 days of the close of the public comment period in (e)(3), EPA will notify the requesting manufacturer of its decision and the basis for granting or denying the request. If the request has been granted, this notification will also identify any additional conditions of use, as determined by the Administrator, that will be included in this 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.

(7) *Identification of information needs.*

(i) Within 90 days following the close of the public comment period in paragraph (e)(6), EPA will determine whether further information is needed to carry out the risk evaluation and notify the requesting manufacturer of its determination. If EPA determines at this time that no further information is necessary, EPA will initiate the risk evaluation, pursuant to paragraph (e)(8) of this section.

(ii) Where additional information needs are identified, EPA will notify the requesting manufacturer and develop a strategy for obtaining the information using available TSCA authorities.

(iii) EPA may delay initiating the risk evaluation for up to 1 year if necessary to obtain information needed to complete the risk evaluation for the chemical substance.

(8) *Initiation of the risk evaluation.*

Within 90 days of the end of the comment period provided in paragraph (e)(6) of this section, unless EPA determined that that additional information would be needed to complete the risk evaluation pursuant to paragraph (e)(7) of this section, then within 1 year of that determination, 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.

(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 without being obligated to pay fees under paragraph (j). 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 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) *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 may supplement the original request with any new information that becomes reasonably available to the requesting manufacturer. At any point prior to the completion of a manufacturer-requested risk evaluation pursuant to this section, the requesting manufacturer 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.

(i) *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.

(j) *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 after EPA has granted the request, but before EPA has initiated the risk evaluation, 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.

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