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The EPA Administrator signed the following *Federal Register* document on June 22, 2017:

Title: **Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act**

Action: Final Rule

FRL: 9964-38

Docket No.: **EPA-HQ-OPPT-2016-0654**

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 702

[EPA-HQ-OPPT-2016-0654; FRL-9964-38]

RIN 2070-AK20

Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: As required under section 6(b)(4) of the Toxic Substances Control Act (TSCA), EPA is issuing a rule that establishes a process for conducting 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 non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. This process incorporates the science requirements of the amended statute, including best available science and weight of the scientific evidence. Risk evaluation is the second step, after Prioritization, in a new process of existing chemical substance review and management established under recent amendments to TSCA. This rule identifies the steps of a risk evaluation process including: scope, hazard assessment, exposure assessment, risk characterization, and finally a risk determination. This process will be used for the first ten chemical substances undergoing evaluation from the 2014 update of the TSCA Work Plan for Chemical Assessments (to the maximum extent practicable). Chemical substances designated as High-Priority Substances during the prioritization process and those chemical

substances for which EPA has initiated a risk evaluation in response to a manufacturer request, will always be subject to this process. The final rule also includes the required "form and criteria" applicable to such manufacturer requests.

DATES: This final rule is effective [*insert date* [*insert number*] *days after date of publication in the* **Federal Register**].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0654, is available at *http://www.regulations.gov* or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202)564-4321; email address: blair.susanna@*epa.gov*.

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SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this Action Apply to Me?

EPA is primarily establishing requirements on the Agency. However, this rule also includes the process and criteria that manufacturers (including importers) must follow when they request an Agency-conducted risk evaluation on a particular chemical substance. This action may, therefore, be of interest to entities that are manufacturing or importing, or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

B. What Action is the Agency Taking?

EPA is establishing, by rule, the process by which the Agency will conduct risk evaluations on chemical substances under TSCA. The rule identifies the necessary components of a risk evaluation, including a scope (including a conceptual model and an analysis plan), a hazard assessment, an exposure assessment, a risk characterization, and a risk determination. The rule also establishes the process by which manufacturers would request an Agency-conducted risk evaluation, and the criteria by which the EPA will evaluate such requests. This rule also incorporates the statutory science requirements, including best available science and weight of the scientific evidence.

C. What is the Agency's Authority for Taking this Action?

EPA is issuing this rule pursuant to the authority in TSCA section 6(b)(4), as amended (15 U.S.C. 2605(b)(4)). See also the discussion in Units II.A. and B.

D. What are the Estimated Incremental Impacts of this Action?

The incremental impacts of this action are the result of the process and requirements that manufacturers (including importers) must perform if they elect to submit a chemical substance for a risk evaluation. EPA has estimated the potential burden and costs associated with the proposed requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance which is available in the docket, is discussed in Unit V. and is briefly summarized here. (Ref. 1).

The total estimated annual burden is 419.2 hours and $282,861, which is based on an estimated per request burden of 83.8 hours.

In addition, EPA's evaluation of the potential costs associated with this action is discussed in Unit V. Since this rule focuses on the activities that a manufacturer must perform, the estimated incremental costs are expected to be *de minimis*.

II. Background

A. Statutory Requirements for Risk Evaluation

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

completion of the risk evaluation. The law also requires that EPA operate in a manner that is consistent with the best available science and make decisions based on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i).

1. Chemical substances to undergo risk evaluation. TSCA section 6(b) identifies the chemical substances that are subject to this process; these are: (1) the ten chemical substances the Agency was required to identify from the 2014 update to the TSCA Work Plan within the first 180 calendar days after the signing of TSCA); (2) the chemical substances determined to be High-Priority Substances through the prioritization process published elsewhere in this **Federal Register**; and (3) chemicals selected in response to a manufacturer request that meets the criteria established by this rule. 15 U.S.C. 2605(b)(4)(C). Assuming EPA receives a sufficient number of compliant requests, the statute specifies that EPA shall ensure that the number of manufacturer-requested evaluations is not less than 25 percent and not more than 50 percent of the number of the on-going "High Priority" risk evaluations. 15 U.S.C 2605(b)(4)(E). Since the number of manufacturer-requested evaluations is expressed as a percentage of the number of High-Priority Substance evaluations, not as a percentage of the total, the number of manufacturer-requested evaluations will likely comprise between 1/5 and 1/3 of the number of total ongoing evaluations, assuming a sufficient number of compliant requests are received. Any manufacturer requested risk evaluations for chemical substances on the 2014 update of the TSCA Work Plan (Ref. 2) will be granted at the discretion of the Administrator, and are exempt from the percentage limitations.

2. Manufacturer-requested risk evaluations. TSCA section 6(b)(4)(C) directs EPA to establish the "form and manner" and "criteria" that govern manufacturer requests that EPA conduct a risk evaluation on a substance that they manufacture. EPA has broad discretion to

establish these criteria, but relatively less discretion over whether to grant requests that comply with EPA's criteria. EPA must grant any request if it determines that it complies with EPA's criteria, until the statutory minimum of 25 percent has been met. Assuming EPA receives requests in excess of this threshold, EPA interprets this provision to grant EPA discretion to determine whether to grant further requests, up to the maximum 50 percent level. In such circumstances, EPA is directed to give preference to manufacturer requests for which EPA determines that restrictions imposed by one or more states have the potential to significantly impact interstate commerce, or health or the environment. 15 U.S.C. 2605(b)(4)(E)(iii).

3. Components of a risk evaluation. The statute identifies the minimum components EPA must include in all chemical substance risk evaluations. For each risk evaluation, EPA must publish a document that outlines the scope of the risk evaluation that EPA expects to conduct, which includes the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations that EPA expects to consider. 15 U.S.C 2605(b)(4)(D). The statute further provides that the scope of the risk evaluation must be published no later than six months after the initiation of the risk evaluation. Id.

Each risk evaluation must also: (1) integrate and assess available information on hazards and exposure for the conditions of use of the chemical substance, including information on specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations; (2) describe whether aggregate or sentinel exposures were considered and the basis for that consideration; (3) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use; and (4) describe the weight of the scientific evidence for the identified

hazards and exposure. 15 U.S.C. 2605(b)(4)(F)(i), and (iii)-(v). The risk evaluation must not consider costs or other non-risk factors. 15 U.S.C. 2605(b)(4)(F)(ii).

4. *Science requirements*. TSCA section 26 requires that, to the extent that EPA makes a decision based on science under TSCA sections 4, 5, or 6, EPA must use scientific standards and base those decisions on the best available science and on the weight of the scientific evidence. 15 U.S.C. 2625(h) and (i). TSCA does not however explicitly define either of these terms. Section 26(h) lists factors for the Agency to consider, as applicable, in employing best available science. These are: (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. As statutory requirements, they apply to EPA's decisions under TSCA sections 4, 5, and 6.

5. Timeframe. TSCA requires that the risk evaluation process last no longer than three years, with a possible additional six-month extension. 15 U.S.C. 2605(b)(4)(G).

6. Opportunities for public participation. The statute requires that the Agency allow for no less than a 30-day public comment period on the draft risk evaluation, prior to

publishing a final risk evaluation. 15 U.S.C. 2605(b)(4)(H).

7. Metals and metal compounds. When evaluating metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 3) or a successor document that addresses metals risk assessment and is peer- reviewed by the Science Advisory Board.

8. Non-vertebrate testing. Although not an explicit section 6 requirement, TSCA imposes new requirements on EPA regarding the reduction of vertebrate testing. Amendments to TSCA section 4 require EPA to "…reduce and replace, to the extent practicable, […] the use of vertebrate animals in the testing of chemical substances…" and to develop a strategic plan to promote such alternative test methods. 15 U.S.C. 2603(h). Under the risk evaluation process, EPA may require development of new information relating to a chemical substance. Prior to developing this information EPA must first take into account reasonably available existing information, and additionally, must encourage and facilitate the use of test methods that reduce or replace the use of vertebrate animals, group chemicals into categories to reduce testing, and encourage the formation of industry consortia to jointly conduct testing and other data gathering to avoid unnecessary duplication of tests.

B. Overview of Final Rule.

This final rule incorporates all the elements required by statute, as discussed in Unit II.A., some additional criteria the Agency plans to include and consider, clarifications for greater transparency, and additional procedural steps to ensure effective and transparent implementation. In response to public comments on the proposal, EPA is, among other things: (1) adding direct references in the final rule to acknowledge the Agency's commitment to implementing the best available science and weight of the scientific evidence

provisions in TSCA, (2) codifying the Agency's commitment to interagency collaboration, (3) allowing manufacturers to limit their requests for EPA-conducted risk evaluations to one or more specified conditions of use, and (4) allowing for risk determinations to be made on individual conditions of use or categories of conditions of use at any time once the Final Scope is published.

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

III. Discussion of Final Rule and Response to Comments.

A. Policy Objectives

The risk evaluation process under TSCA will provide the basis for the EPA's determination as to whether a chemical substance presents an unreasonable risk of injury to health or the environment. The overall objective of this action is to codify the process by which the Agency evaluates risks from chemical substances under TSCA section 6. In this rule, the Agency details those components of TSCA risk evaluation and key factors that EPA deems are necessary to consider in each risk evaluation to ensure that the public has a full understanding of how risk evaluations will be conducted and to provide predictability in how they will be conducted. However, EPA is not establishing highly detailed provisions that will address every eventuality or possible consideration that might arise. Due to the rapid advancement of the science of risk evaluation and the science and technology that inform risk evaluation, this rule seeks to balance the need for the risk evaluation procedures to be transparent, without unduly restricting the specific science that will be used to conduct the

evaluations, allowing the Agency flexibility to adapt and keep current with changing science as it conducts TSCA evaluations into the future.

B. Scope of Evaluations

TSCA requires risk evaluations to determine whether or not a chemical substance presents an unreasonable risk of injury to health or the environment under the conditions of use, with conditions of use being defined 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).

In the proposed rule, EPA explained that it interpreted TSCA to require that risk evaluations encompass all manufacture, processing, distribution in commerce, use, and disposal activities that constitute the conditions of use within the meaning of TSCA section 3. EPA further proposed that the conditions of use would need to encompass all known, intended, and reasonably foreseen activities associated with the subject chemical substance. EPA also noted, however, that a use or other activity constitutes a condition of use under the definition only if EPA determines that it does, and that EPA has authority to exercise judgment in making its determination of whether a condition of use is known, intended, or reasonably foreseen.

This was one of the issues on which EPA received the most comments. Comments covered a number of considerations regarding conditions of use: how the Agency will define "the conditions of use", how the Agency will scope conditions of use (e.g., are there conditions of use which will not be included in the Scope of the risk evaluation for one reason or another), and finally how the Agency will treat the conditions of use identified in

the scope, in the final risk determination. EPA discusses the first two considerations in this unit; the third consideration will be discussed in the risk determination Unit III.G.1.e.

In defining conditions of use, many commenters raised concern about EPA's interpretation that "the conditions of use" must include "all conditions of use." Concerns were raised in this regard was specifically about the ability of EPA to meet the statutory risk evaluation deadlines if all intended, known and reasonably foreseen activities must be considered conditions of use, and that attempting to identify every activity relating to the chemical substance was unnecessary and impractical. Concerns were also raised about ensuring that EPA can act promptly to address any unreasonable risks identified for particular conditions of use. Commenters who agreed with the proposed interpretation of "all conditions of use" stated that the law in a number of locations signals the intent that EPA evaluate all activities associated with the chemical. The identified locations include the section on Final Agency Action which states that decisions will be on a "chemical substance" without mention of condition of use, indicating that EPA must consider all conditions of use (15 U.S.C. § 2605(i)), and the requirement to account for the "likely duration, intensity, frequency, and number of exposures under the conditions, where relevant" (15 U.S.C. § 2605(b)(4)(F)(iv)), which refers to the consideration of whether a combination of activities involving the chemical substance presents a risk, and therefore EPA must look at the full spectrum of the activities associated with a chemical (all intended, known, or reasonably foreseen manufacturing, processing, distribution, use and disposal).

As EPA acknowledged in the proposal, different interpretations of the statute are possible. Given the strength and variety of the concerns presented in the comments, EPA has reevaluated its proposal. Accordingly, EPA went back to the direction on risk evaluation

provided in section 6(b) of the statute and legislative history, and developed an approach to the term, "the conditions of use" that is firmly grounded in the law, while accounting for the various policy considerations necessary for effective implementation of section 6. EPA's final approach is informed in part by the legislative history of the amended TSCA, which explicitly states that the Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical, in order to ensure that the Agency's focus is on the conditions of use that raise the greatest potential for risk. See, June 7, 2016 Cong Rec, S3519 - S3520.

In sum, EPA's overall objective of this rule is to ensure that it is able to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance as a whole, and that it always includes an evaluation of the conditions of use that raise greatest potential for risk. EPA wants also to ensure that the Agency can effectively assess, and where necessary, regulate chemical substances, within the statutory deadlines. These same principles will also serve to guide EPA's implementation of the procedures.

To begin, EPA will identify the "circumstances" that constitute the "conditions of use" for each chemical substance on a case-by-case basis. TSCA defines a chemical's "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). While EPA interprets this as largely a factual determination—*i.e.*, EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition—the determination will inevitably involve the exercise of some discretion. As

EPA interprets the statute, the Agency is to exercise that discretion consistent with the objective of conducting a technically sound, manageable evaluation to determine whether a chemical substance – not just individual uses or activities – presents an unreasonable risk. In that regard, EPA will be guided by its best understanding, informed by legislative text and history, of the circumstances of manufacture, processing, distribution in commerce, use and disposal Congress intended EPA to consider in risk evaluations.

For most chemical substances EPA expects to make this determination primarily during the prioritization of a chemical substances. For chemicals that are the subject of a manufacturer request (which are not subject to prioritization), EPA intends to make this determination as part of the process for determining whether the request satisfies EPA's criteria, as discussed in greater detail in Unit III.G.

Although EPA intends this to primarily be a case-by-case determination, as discussed in greater detail in Unit III.B.1, based on legislative history, statutory structure and other evidence of Congressional intent, EPA has identified certain activities that may generally not be considered to be conditions of use. As EPA gains experience in conducting risk evaluations, EPA may determine that other activities do not constitute conditions of use, based on the same type of analysis of Congressional intent. Second, in developing the scope of the risk evaluation, TSCA section 6(b)(4)(D) requires EPA to identify "the conditions of use that the Agency expects to consider in a risk evaluation," suggesting that EPA is not required to consider all conditions of use. Consequently, EPA may, on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern, and consequently merit an unreasonable risk determination. For example, EPA may, on a case-

by-case basis, exclude uses that EPA has sufficient basis to conclude would present only "*de minimis*" exposures. This could include uses that occur in a closed system that effectively precludes exposure, or use as an intermediate. During the scoping phase, EPA may also exclude a condition of use that has been adequately assessed by another regulatory agency, particularly where the other agency has effectively managed the risks. EPA elaborates further on this step in Unit III.B.2.

EPA intends to identify any conditions of use excluded during these first and second steps in the draft scope, along with the basis for EPA's preliminary determination, to provide the public with an opportunity to comment on the exclusions. The final scope, which specifies the conditions of use that EPA expects to consider in the risk evaluation, will also identify whether particular conditions of use have been excluded as a result of this process, along with the Agency's rationale.

Finally, consistent with its original proposal, EPA may conduct its risk evaluations in stages. While the proposal only addressed the situation in which EPA determined that risk mitigation was necessary to address an unreasonable risk from a chemical substance under certain conditions of use, EPA has extended the logic in the final rule to apply whenever EPA has sufficient information to support a determination as to whether a chemical substance presents an unreasonable risk under particular conditions of use. Thus, at any point after EPA has issued its final scope document, in cases where EPA has sufficient information to determine whether or not the chemical substance presents an unreasonable risk under particular conditions of use, the Agency may issue an early determination for that subset of conditions of use, while EPA continues to evaluate the remaining conditions of use. All early determinations would be portions of the final, complete risk evaluation and would

therefore be made using the procedures applicable to TSCA risk evaluations established in this rule. This would include the requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period, and the regulatory requirement for peer review. This may result in separate peer reviews for the separate determinations.

In the interest of efficiency, EPA envisions that, in general, it would attempt to identify the subset of conditions of use that are candidates for an early determination as part of the draft scope document. In such cases, EPA may publish its draft risk evaluation for public comment along with the final Scope document. Depending on the information received during the comment period, EPA would either determine that it needed to continue to evaluate those conditions of use, or proceed to issue final determinations for those conditions of use.

1. *Exclusions from the Definition of Conditions of Use.* As noted, the statute grants EPA the discretion to determine the circumstances that are appropriately considered to be the chemical's "conditions of use." In exercising that discretion, for example, EPA would not generally consider that a single unsubstantiated or anecdotal statement (or even a few isolated statements) on the internet that a chemical can be used for a particular purpose would necessitate concluding that this represented part of the chemical substance's "conditions of use." As a further example, although the definition could be read literally to include all intentional misuses (e.g., inhalant abuse), as a "known" or "reasonably foreseen" activity in some circumstances, EPA does not generally intend to include such activities in either a chemical substance's prioritization or risk evaluation. EPA's judgment is supported by the legislative history, and public comment suggesting that "the term 'conditions of use' is not intended to include 'intentional misuse' of chemicals." See, for example Senate Report

114-67, page 7. Without these exclusions, the concept of "conditions of use" would likely result in no meaningful limitation on EPA risk evaluations, and risk evaluations could present unmanageable challenges – an outcome that EPA does not expect Congress intended.

Similarly, the statute is ambiguous as to whether the conditions of use identified by EPA should include the circumstances associated with activities that do not reflect ongoing or prospective manufacturing, processing, or distribution, which EPA will refer to as "legacy uses." The statute is also ambiguous as to disposals from such uses (e.g., the future disposal of insulation that contains a chemical substance that is no longer manufactured, processed, or distributed for use in insulation), which EPA will call "associated disposal," and disposals that have already occurred (e.g., a chemical substance currently in a landfill or in groundwater), which EPA will call "legacy disposal." No statutory text expressly addresses these issues. The absence of express statutory text on legacy use, associated disposal, and legacy disposal, as well as the plain language in "conditions of use" charging EPA to determine the circumstances appropriately considered to be the "conditions of use," leads the Agency to resolve the statutory ambiguity by considering all the tools of statutory interpretation (e.g., reliance on legislative history, and general maxims of statutory construction).

EPA interprets the mandates under section 6(a)-(b) to conduct risk evaluations and any corresponding risk management to focus on uses for which manufacturing, processing, or distribution in commerce is intended, known to be occurring, or reasonably foreseen to occur (i.e., is prospective or on-going), rather than reaching back to evaluate the risks associated with legacy uses, associated disposal, and legacy disposal, and interprets the definition of "conditions of use" in that context. For instance, the conditions of use for purposes of section

6 might reasonably include the use of a chemical substance in insulation, where the manufacture, processing, or distribution in commerce for that use is prospective or on-ongoing, but would not include the use of the chemical substance in previously installed insulation, if the manufacture, processing or distribution for that use is not prospective or on-going. In other words, EPA interprets the risk evaluation process of section 6 to focus on the continuing flow of chemical substances from manufacture, processing and distribution in commerce into the use and disposal stages of their lifecycle. EPA believes the statute is better interpreted to focus on the prospective flow of the chemical substance. That said, in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposures resulting from non-legacy uses.

Overall, EPA has determined that the statutory text better supports a prospective interpretation. Section 3 defines the "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." (emphasis added). The "to be" phrasing suggests that the term is focused prospectively. Moreover, throughout the legislative history, there are a number of references to TSCA as a statute for the regulation of chemicals "in commerce," suggesting the intent to focus on current activities associated with chemicals rather than legacy issues. In addition, EPA notes that section 6(a) of TSCA does not authorize EPA to directly regulate non-commercial use, meaning that EPA would not have an effective tool to address risks found to arise from uses in consumer settings if there were no on-going commercial manufacture, processing or distribution.

EPA's interpretation finds support in the general presumption against construing a statute (or implementing regulation) to be retroactive or have retrospective effect. While Congress can make a law retroactive, absent clear intent from Congress, courts will not hold a statute to be retroactive, or uphold an agency regulation that seeks to have such an effect. *Republic of Iraq v. Beaty*, 556 U.S. 848 at 862 (2009) (citing to *Landgraf v. Usi Film Products*, 511 U.S. 244, 267–68 (1994). See also, *Bowen v. Georgetown Univ. Hosp*., 488 U.S. 204, 208 (1988) (citing several sources). This general presumption also extends to statutes that affect "vested rights and past transactions," which have been considered to be retroactive (or "retrospective") in nature. E.g., *Landgraf*, 511 U.S. at 268–69, 296 (quotation marks and citations omitted) (citing several other Supreme Court cases using alternate formulations of this principle).

Finally, even if these activities were not excluded from the definition of conditions of use, EPA generally expects that it would exercise its discretion under section 6(b)(4)(D) to exclude them from the scope of risk evaluations, as discussed in section B.2., below.

2. *Conditions of use that may be excluded from the Scope of the risk evaluation.* In exercising its discretion under section 6(b)(4)(D), EPA believes it is important for the Agency to have the discretion to make reasonable, technically sound scoping decisions in light of the overall objective of determining whether chemical substances in commerce present an unreasonable risk. For example, EPA intends to exercise discretion in addressing circumstances where the chemical substance subject to scoping is unintentionally present as an impurity in another chemical substance that is not the subject of the pertinent scoping. 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

evaluations 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. (EPA has previously taken an analogous approach, in requiring chemical testing of certain chemical substances under 40 CFR Part 766, based on the potential for the chemical substance to be manufactured in such a manner as to be contaminated with dioxins.) In still other cases, EPA may choose not to include a particular impurity within the Scope of any risk evaluation, where EPA has a basis to foresee that the risk from the presence of the impurity would be
'*de minimis'* or otherwise insignificant. Finally, as stated, EPA received a number of comments offering ideas regarding conditions of use that should not be considered in a risk evaluation, for example, on the ground that certain uses are not "reasonably foreseen." Some of the many uses that commenters asked to be excluded from a risk evaluation include: uses where other agencies hold jurisdiction, misuse, illegal use, speculative future conditions of use, uses that are inconsistent with labeling requirements or PPE requirements, chemicals used in articles or replacement parts, uses that are inconsistent with manufacturers' instructions, accidental conditions of use of a chemical, or uses where residuals from an industrial process are completely destroyed. In connection with these suggestions, several of these commenters also requested that EPA clearly define precisely how the Agency will determine whether a condition of use is "known or reasonably foreseen."

At this stage of EPA's implementation, EPA believes that it would be premature to definitively exclude a priori specific conditions of use from risk evaluation. For the same reason, EPA believes that it would be premature to establish a specific test or restrictive definition to determine whether a condition of use is "reasonably foreseen." The Agency is

committed to exercising its discretion to determine the conditions of use in a reasonable manner and will not base this determination upon hypotheticals or conjecture. The identification of "reasonably foreseen" conditions of use will necessarily be a case by case determination, and will be highly fact-specific. Sources of facts to support such determinations may include known activities associated with similar chemicals, knowledge of a chemical's properties that may allow it to replace a function currently being performed by non-chemical means, or information on research and development activities applying a chemical substance to a particular new use. It is reasonable to foresee a condition of use, for example, where facts suggest the activity is not only possible but, over time under proper conditions, probable.

As EPA gains experience in conducting risk evaluations, it will likely develop additional scoping principles, consistent with the discussion in this preamble. EPA has issued Guidance to Assist Interested Persons in Developing and Submitting Draft Risk Evaluation Under the Toxic Substances Control Act and section 26(l) requires EPA to reevaluate guidance every 5 years. This document may be the appropriate venue for EPA to provide additional transparency regarding conditions of use included/excluded as a part of scoping as the Agency becomes better versed in this process.

C. General Provisions.

The general provisions of the final rule outline the purpose, scope, applicability and enforcement of this rule.

D. Definitions.

TSCA defines a number of key terms necessary for interpretation of the new law, and the statutory definitions apply to this rule. To increase clarity and transparency, EPA has

included a number of additional definitions in the rule. In the proposed rule, EPA asked for comments specifically on whether to codify definitions of terms including “best available science”, “weight- of- the- scientific evidence”, “sufficiency of information”, “unreasonable risk”, and “reasonably available information,” among others. EPA identified the sources of possible definitions, and in some instances provided extensive discussion of its current interpretation of the terms. EPA also encouraged commenters to suggest alternative definitions the Agency should consider for codification in this rule.

EPA received a number of comments on this subject; in general, many comments acknowledged that there are numerous ways these phrases can be defined and ultimately implemented. Many also acknowledged that the science is changing and the Agency must maintain flexibility to implement advancing and novel science. Some commenters agreed with EPA’s proposed conclusion that not defining the terms allows for flexibility to change as the science changes and that strict definitions may impede TSCA implementation. A number of comments discussed the legislative history behind these terms, specifically the fact that previous versions of the statute did include some of these definitions and that they were removed in the final version. Other commenters argued that since these terms are not defined in the statute and there is no requirement in the statute to define them by rule, there was no Congressional intent to codify definition of these terms in this rule. Additionally, it was reasoned that any codified definitions would apply not only to TSCA section 6 actions and rules, but also to TSCA sections 4 and 5, and potentially other applications outside of TSCA. They argued this makes it much more difficult to develop and implement universally appropriate definitions.

A significant number of commenters did encourage EPA to define, or at the very

least, to provide additional principles and concepts that will be applied to implement these terms, arguing that this will add transparency and better articulate how EPA will implement the scientific criteria of the statute. Some commenters stated that the definitions of these terms have not changed with changing science, only the data sets used to inform the definitions. Other commenters, who agreed these terms do have a number of different meanings believed it was therefore more important to define them in this rule so the public knew which definition would be applied. Commenters also stated these terms are the "cornerstones" of risk evaluations under TSCA, and definitions were necessary to alleviate potential confusion in implementation of these requirements. Many commenters who believed it is necessary for EPA to define these terms did include proposed definitions and/or descriptions.

EPA has chosen to only define terms in this final rule that appear in the statute, including best available science, reasonably available information, and weight of the scientific evidence, among others. EPA agrees with many of the public comments that the definitions of these terms in the final rule will instill confidence, increase transparency, and provide the public with assurance that EPA will adhere to the requirements of the statute. Based on review of the public comments received, EPA has also revised the proposed definitions to increase their clarity, while also adding additional discussion in the preamble .

EPA will first discuss definitions included in the regulation (in the order they appear in the regulation), and then will discuss additional terms that have not been codified, but are important components of the risk evaluation process.

1. *Aggregate exposure*. TSCA requires EPA, as a part of the risk evaluation, to document whether the Agency has considered aggregate exposure, and the basis for that

decision. 15 U.S.C. 2605(b)(4)(F)(ii). This term is not statutorily defined; however, EPA has defined aggregate exposure to be consistent with current Agency policies and practices. "Aggregate exposure" means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways (Ref.4). This is consistent with the proposed rule and consistent with agency policy.

2. *Best available science.* Section 26(h) of amended TSCA requires that "in carrying out sections 4, 5, and 6, to the extent that the Administrator makes a decision based on science, the Administrator shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or models, employed in a manner consistent with the best available science." As stated, many commenters encouraged EPA to codify a definition of the "best available science." In response to these comments, EPA determined that 'best available science' is an integral component of section 6 risk evaluations, and has incorporated a definition of 'best available science' into the regulatory text. The first part of the definition originates from the Safe Drinking Water Act (SDWA) (42 U.S.C. section 300f *et seq*.) and is also included in the EPA's Information Quality Guidance (Ref. 5). The SDWA definition was cited by a number of commenters, and EPA agrees this definition, already in use at the Agency, is appropriate. The second part of the definition is taken directly from TSCA section 26(h), which identifies mandatory approaches to fulfilling the science standards under TSCA. By basing its definition of 'best available science' on these two sources, EPA believes that the Agency is remaining consistent with the current approach already used Agency-wide, while also acknowledging the specific standards under TSCA.

The final rule defines "best available science" as science that is reliable and unbiased. This involves the use of supporting studies conducted in accordance with sound and

objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable: –

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

3. *Conditions of use* as defined in 15 U.S.C. 2602(4), means the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of. This definition was not included in the proposed rule, but has been added for clarity. Additional discussion of conditions of use can be found in Unit B.

4. *Pathways.* Pathways of exposure refers to the mode through which one is exposed

to a chemical substance, including but not limited to: food, water, soil, and air (Ref. 4). This definition is consistent with EPA's policies and practices, and did not change from the proposed rule.

5. *Potentially exposed or susceptible subpopulations.* TSCA requires EPA to evaluate risk to "potentially exposed or susceptible subpopulation[s]" identified as relevant to the risk evaluation by the Administrator, under the conditions of use. 15 U.S.C 2605(b)(4)(A). TSCA defines this as "the term 'potentially exposed or susceptible subpopulation' means a group of individuals within the general population identified by the EPA who, due to either greater susceptibility or greater exposure, may be at greater risk than the general population of adverse health effects from exposure to a chemical substance or mixture, such as infants, children, pregnant women, workers, or the elderly." 15 U.S.C. 2602(12). EPA proposed a definition to clarify how the Agency interprets this provision. Specifically, EPA proposed to substitute the phrase "including but is not limited to" for the statutory phrase "such as," to clarify that the statutory list of potential subpopulations is not exclusive. EPA also proposed to include additional examples of subpopulations that have been previously considered. In response to comments, the final rule simply codifies the statutory definition without revision.

EPA received a number of comments regarding this definition. Some stated that EPA was correct in expanding and clarifying the definition in the proposed rule, while others stated that EPA should use the statutory definition. Many comments that supported the proposed definition also identified other subpopulations that EPA should include. EPA's view of the interpretation of the statutory definition has not changed since proposal -- EPA interprets the statutory definition broadly and believes it does not prevent EPA from including any subpopulation that may be at greater risk due to greater susceptibility or

exposure, or from identifying additional subpopulations other than those listed in the statute, where warranted. The definition in the final rule uses the statutory definition because, due to EPA's broad interpretation, EPA does not think that it limits any consideration of a particular subpopulation. Also, regarding EPA's proposed inclusion of more examples than those provided by the statute (e.g., life-stage, age, gender, geography), and in reading public comments, which listed numerous other important subpopulations EPA should consider, it was clear that it would be difficult for the Agency to list all the potential subpopulations that the Agency might have reason to include in a risk evaluation. Codification of the statutory definition does not limit the subpopulations that may be evaluated and ensures there is no misconception that a partial list was intended as a deliberate exclusion of other subpopulations.

6. *Reasonably available information.* TSCA section 26(k) (15 U.S.C. 2625(k)) states that in carrying out risk evaluations, EPA shall consider information that is "reasonably available," but the statute does not further define this phrase. EPA is defining "reasonably available information" to mean information that EPA possesses, or can reasonably obtain and synthesize for use in risk evaluations, considering the deadlines for completing the evaluation. However, there is a preference for reasonably available information that is consistent with the required quality standards. Information that meets the terms of the preceding sentence is reasonably available information whether or not it is claimed as confidential business information. This definition is slightly revised from the proposed definition.

First, EPA deleted the word "existing" to address concerns that this would prevent the Agency from considering (or requiring) data generated in response to EPA data gathering,

including testing, authorities. Several commenters encouraged EPA to take full advantage of its new information gathering authorities and not limit the basis of its decisions to "existing" information. EPA agrees that it makes sense to view information that can be obtained through testing as "reasonably available" in some instances – especially information that can be obtained through short-term testing, where it can be obtained within the relevant statutory deadlines and the information would be of sufficient value to merit the testing. As discussed in a related rulemaking on prioritization under TSCA, EPA will seek to generally ensure that sufficient information to complete a risk evaluation exists and is available to the Agency prior to initiating the evaluation. The proposed definition was drafted to reflect that intention. However, EPA also recognizes that there may be circumstances where additional information may need to be developed within the time frames of the risk evaluation process. This may include information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques). While EPA disagrees that its original definition would have precluded the generation of additional data, to avoid any confusion, EPA has modified the definition to clarify the point. Note that EPA will, as appropriate, also require longer-term testing, and at times will need to do so to address data gaps. However, EPA does not think information that could be generated through such testing should be viewed as "reasonably available". EPA will tailor its information gathering efforts as appropriate.

Second, EPA added a statement regarding CBI to clarify to the public that EPA does consider CBI under section 14 of TSCA to be "reasonably available," and will utilize it in risk evaluations where relevant.

7. *Routes*. The final rule defines routes of exposure to mean the particular manner

which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (Ref. 4). This definition is consistent with EPA's policies and practices and with the proposed definition.

8. *Sentinel exposure*. The final rule defines sentinel exposure to mean the exposure to a single chemical substance that represents the plausible upper bound of exposure relative to all other exposures within a broad category of similar or related exposures. As mentioned in the proposed rule, this term previously had not been defined by the Agency. In light of the comments received, many of which requested revisions to the proposed definition, EPA believes it most appropriate to revise the definition in the proposed rule. The majority of comments explained that the concept of sentinel exposures is narrower than the definition EPA had proposed ("the exposure of greatest significance, which may be the plausible maximum exposure"); rather, as one comment explained, sentinel exposures are employed to represent broad categories of use so that the assessor does not have to go into each specific subcategory of use. While sentinel exposures do represent upper-bound exposures—which is part of what EPA proposed—it is the upper bound within those broad use categories. Under this approach, because the exposures are expected to be much greater than other sources or pathways, if the margin of exposure is at an acceptable level, there is no need to specifically evaluate the other individual exposure pathways in the category. A number of commenters also suggested that EPA adopt the approach to 'sentinel exposure' used by the European Union's (EU) European Chemicals Agency (ECHA) Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program and Health Canada (Ref. 6 and 7). The final definition, although not the same as the one used by ECHA and Health Canada, more closely tracks their approach. Specifically, the definition seeks to address situations including but not

limited to: (1) The same chemical substance is added to a number of related products, and EPA is evaluating exposure to the chemical substance in these related products under the same exposure scenario (e.g., adults who could use these products for the same task). If EPA identifies and evaluates the product associated with the upper bound of exposure from use of these products, then EPA could reach risk conclusions for the chemical substance in the entire category of these products, because the range of potential exposures is no greater than the magnitude of the exposure to the chemical substance in the upper-bound product. (2) A number of different workers are exposed to the same chemical substance. If EPA identifies or evaluates the worker whose exposure represents the upper bound of exposure, EPA would have confidence that the other workers exposed would be less exposed than the worker with the upper bound or "sentinel" exposure.

In the proposed rule, EPA used the phrase "maximum exposure" in defining sentinel exposure. This phrase has been changed to "upper bound of exposure" in the final rule. This change was a result of public comment that suggested that the term "maximum" could indicate that EPA intended to use only the 99.99^{th} percentile exposure. This was not EPA's intent, and so EPA has substituted the phrase "upper-bound of exposure," which is consistent with EPA's existing practice, and allows EPA the flexibility to consider the available data and its quality in determining the appropriate exposure scenario (e.g., sentinel exposure scenarios).

9. *Uncertainty and variability*. The statute requires EPA to consider "the extent to which the variability and uncertainty…are evaluated and characterized." 15 U.S.C. 2625(h). EPA proposed definitions for both "variability" and "uncertainty" based on existing Agency guidance (Framework for Human Health Risk Assessment). The final rule adopts the

proposed definition of “uncertainty” with minor modification. EPA added the phrase “the real world” to exactly reflect the definition in Agency guidance. In the final rule, uncertainty means the imperfect knowledge of the real world or lack of precise knowledge of the real world either for specific values of interest or in the description of the system (Ref. 8). The final rule adopts the proposed definition of “variability” without modification. The regulation thus states: “Variability” means the inherent natural variation, diversity, and heterogeneity across time and/or space or among individuals within a population (Ref. 8). Both definitions are consistent with EPA’s policies and practices.

10. *Weight of the scientific evidence.* The Agency is required by the statute to use a weight of scientific evidence approach in a risk evaluation and the Agency is codifying a definition of this term in this final rule. In responding to public comment, EPA notes that inclusion of the definition will provide the much requested transparency to the public regarding the processes for how the Agency reviews scientific information used in risk evaluations without stifling scientific advances. In the preamble to the proposed rule, EPA provided an extensive discussion of how the weight of the scientific evidence is applied by EPA and the National Toxicology Program of the National Institutes of Environmental Health. This discussion formed part of the basis for the definition EPA is promulgating in this final rule.

The application of weight of the scientific evidence has generated much discussion in the scientific community, and EPA agrees with the National Academies who stated “because scientific evidence use in weight of the scientific evidence (WoSE) evaluations varies greatly among chemical and other hazardous agents in type, quantity and quality, it is not possible to describe the WoSE evaluation in other than relative general terms” (Ref. 9). Application of

weight of the scientific evidence analysis is an integrative and interpretive process. It is more than a simply tallying of the number of positive and negative studies. It also is applicable to both human health and ecological risk evaluations.

There are certain principles of weight of the scientific evidence that are universal, including foundational considerations, such as objectivity and transparency, and the general process. This process starts with assembling the relevant information, evaluating the information for quality and relevance, and synthesizing and integrating the different lines of evidence to support conclusions (Ref. 10). Given these overarching and inclusive principles, EPA does not think that providing a general definition restricts flexibility or scientific advancement. For the purposes of this rule the definition EPA is adopting states: "Weight of the scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance." This definition was suggested by a few public commenters, it is consistent with practices under TSCA before it was amended, and was generally outlined in the lengthy discussion in the proposal. The bulk of the definition, aside from the phrase "applied manner suited to the nature of the evidence or decision" clarification, is taken directly from TSCA's legislative history. See Congressional Record at S3519, June 7, 2016. The additional phrase was added to be consistent with the concept (also discussed in the proposal) that the components of its risk evaluations will be "fit-for-purpose." As explained in the proposed rule at 82 Fed. Reg. 7566, all conditions of use will not warrant the same level of evaluation, and EPA expects that it

may, in some cases, be able to reach conclusions without extensive or quantitative evaluations of risk. The addition of this phrase to the definition is intended to clarify that different weight of the scientific evidence review methods may be appropriate for different information, types of evaluations, or decisions. Specifically, fit-for-purpose means that while EPA will always apply the principles contained in the definition, the depth or extent of the analysis will be commensurate with the nature and significance of the decision.

11. Systematic Review. EPA requested comment on the need for regulatory text prescribing a specific systematic review approach for hazard identification, including the appropriateness of elements that might be included or concerns about codifying an approach. Commenters both supported and opposed the inclusion of systematic review in the rule text. Those opposing the codification of systematic review argued that EPA should retain flexibility and the ability to change the process as improved methods for systematic review are developed. Some commenters did encourage a description of the intended approach in the preamble, but suggested that EPA reserve the specific process for guidance. Those in support of codifying a description of systematic review in the rule text stated that inclusion would increase transparency and would provide the public with an indication of how the statutory requirement of weight of the scientific evidence, requirements of sections 6 and 26, and an integral component of systematic review, will be applied.

EPA intends to use the systematic review approach, described in the proposed rule, but is not codifying a definition in the regulatory text. To be clear, although EPA asked for comment on the need for regulatory text for systematic review on hazard identification specifically, EPA will not limit the use of this approach solely to the hazard assessment, but will use it throughout the risk evaluation process. The inclusion of a description of systematic

review in the preamble is the most appropriate approach in light of public comment and the requirements of the statute. First, systematic review is not required under the statute, only a weight of the scientific evidence analysis. The definition the Agency is adopting for "weight of the scientific evidence" uses the phrase "systematic review," which addresses to some extent the commenters who favored including the concept in this regulation.

EPA sees weight of the scientific evidence approach as an interrelated part of systematic review, and further believes that integrating systematic review into the TSCA risk evaluations is critical to meet the statutory requirements of TSCA. Although, as EPA discusses elsewhere in this preamble, there are universal components of systematic review that EPA intends to apply in conducting risk evaluations, this is one area where EPA concluded it would be premature to codify specific methods and criteria that may change as the Agency gains more experience conducting TSCA risk evaluations. As requested by commenters, EPA does believe the addition of discussion of the systematic review approach the Agency intends on utilizing is necessary for transparency, and so provides the description herein. Section 26(l) also requires EPA to develop and revise Agency guidance. The Agency intends to provide further details on systematic review and weight of scientific evidence approaches under TSCA in future guidance documents.

As defined by the Institute of Medicine (Ref. 11) systematic review "is a scientific investigation that focuses on a specific question and uses explicit, pre-specified scientific methods to identify, select, assess, and summarize the findings of similar but separate studies. The goal of systematic review methods is to ensure that the review is complete, unbiased, reproducible, and transparent" (Ref. 11).

The principles of systematic review have been well developed in the context of

evidence-based medicine (e.g., evaluating efficacy of medical interventions tested in multiple clinical trials) (Ref. 12) and are being adapted for use across a more diverse array of systematic review questions, through the use of a variety of computational tools. For instance, the National Academies' National Research Council (NRC) has encouraged EPA to move towards systematic review processes to enhance the transparency of scientific literature review that support chemical-specific risk assessments to inform regulatory decision making (Ref. 13). Key elements of systematic review include:

- A clearly stated set of objectives (defining the question);
- Developing a protocol which describes the specific criteria and approaches that will be used throughout the process;
- Applying the search strategy criteria in a literature search;
- Selecting the relevant papers using predefined criteria;
- Assessing the quality of the studies using predefined criteria;
- Analyzing and synthesizing the data using the predefined methodology;
- Interpreting the results and presenting a summary of findings (Ref. 14)

12. Sufficiency of information. EPA did not propose to codify this phrase, but discussed it in the context of having "enough" information to conduct a risk evaluation within the statutory timeframe. However, EPA also specifically requested comment on whether to define sufficiency of information. Commenters who opposed codifying a definition stated that the phrase was "vague" and could have a number of definitions and that the information needs for chemical risk evaluations can vary significantly, so not one definition would be appropriate. Commenters who supported codifying a definition of this phrase stated that, specifically for risk evaluation conducted and submitted by third parties,

knowledge of what constitutes sufficient information is necessary. Consistent with the proposed rule, the final rule does not codify this term because EPA agrees that the information required for chemical risk evaluations can be highly variable, and that given the case-by-case nature of the hazard and exposure scenarios, it is difficult to have an overarching definition of "sufficient information" applicable to all evaluations. EPA does not believe that the definitions offered by the commenters would provide any greater clarity that would effectively inform third party risk evaluations and expansion of this concept is more appropriate for the statutorily required guidance documents.

13. Unreasonable risk. In the proposed rule, EPA said that the Agency did not think it was appropriate to define "unreasonable risk" because each risk evaluation will be unique. For example, defining specific risk measures for use in all risk evaluations would be inappropriate to capture the broad set of health and environmental risk measures and information that might be relevant to chemical substances. In the preamble to the proposed rule, EPA did discuss some of the considerations the Agency will use in making a risk determination. The public overwhelmingly agreed with the proposed approach. EPA did take public comment on this approach and the public agreed that a definition was not appropriate, but appreciated EPA's approach to including considerations.

For the final rule. the Agency will be taking the same approach, and has identified, a revised list of some of the considerations that the Agency will use in making a risk determination. This is not intended as an exhaustive list, but merely identifies some of the considerations that are likely to be among the most commonly used. However, the list of considerations has changed slightly in response to public comment. In the proposed rule preamble a few considerations were too specific and were not expected to be widely

applicable to TSCA risk evaluations. For example, the proposed rule included the specific mention of margin of exposure (MOE), which is just one approach for risk characterization. EPA acknowledges that MOE is just one of several approaches to risk characterization, and agrees that it does not make sense to single out this one particular approach. There will be risk scenarios where one approach may be better than another and, as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. The proposed preamble had also included the consideration of cumulative exposure in making a risk determination. A number of commenters pointed out, this is not a requirement under the statute; EPA agrees that this may not be widely applicable to many TSCA risk assessments, and so EPA has not included it in the list below. Additionally, commenters correctly pointed out that EPA did not mention environmental risks in the proposed definition. Considerations of environmental hazards and exposures have been added.

To account for the number of different risk characterization approaches and for changing science, EPA will not include any specific definition in this final rule. To make a risk determination, EPA may weigh a variety of factors in determining unreasonable risk. The Administrator will consider relevant factors including, but not limited to: the effects of the chemical substance on health and human exposure to such substance under the conditions of use (including cancer and non-cancer risks); the effects of the chemical substance on the environment and environmental exposure under the conditions of use; the population exposed (including any susceptible populations), the severity of hazard (the nature of the hazard, the irreversibility of hazard), and uncertainties.

E. Timing of Risk Evaluations

A risk evaluation is initiated upon the final designation of a high priority substance at the completion of the prioritization process or through the completed manufacturer request process. A risk evaluation is complete upon the publication of the final risk evaluation, which includes the final risk determination for all the conditions of use identified in the Scope document. As indicated, the statute requires EPA to complete risk evaluations within three years, with the possibility of a single six-month extension. This rule adopts these timeframes without modification or elaboration.

F. Chemical Substances for Risk Evaluation

As identified previously, chemical substances that will undergo risk evaluation can be put into three groups: (1) the first ten chemical substances the Agency is required to identify within the first 180 calendar days of enacting the amendments to TSCA (15 U.S.C. 2605(b)(2)); (2) the chemical substances determined as High-Priority Substances through the prioritization process proposed in a separate rulemaking; and (3) chemical substances requested by manufacturers, when the requests meet the criteria for EPA to conduct an Agency risk evaluation.

Public comment requested that EPA be explicit about what constitutes a chemical substance under TSCA. The statute defines a chemical substance to mean any organic or inorganic substance of a particular molecular identity, including: (1) any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring nature, and (2) and element or uncombined radical. Chemical substances do not include: (1) any mixture, (2) any pesticide (as defined in the Federal Insecticide, Fungicide, and Rodenticide Act) when manufactured, processed, or distributed in commerce for use as a pesticide, (3) tobacco or any tobacco product, (4) any source material, special nuclear

material, or byproduct material (as such terms are defined in the Atomic Energy Act of 1954 and regulations issued under such Act), (5) any article the sale of which is subsequent to the tax imposed by section 4181 of the Internal Revenue Code of 1954 (determined without regard to any exemptions from such tax provided by section 4182 or 4221 or any other provision of such Code), and (6) any food, food additive, drug, cosmetic, or device (as such terms are defined in section 201 of the Federal Food, Drug, and Cosmetic Act) when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device. 15 U.S.C. 2602(2)(B). The list constitutes what is commonly referred to as "non-TSCA uses." It may be appropriate for EPA to consider potential risk from non-TSCA uses (as identified above) in evaluating whether a chemical substance presents an unreasonable risk, although these uses would not be within the scope of the risk evaluation. EPA would explain the basis for such consideration in any risk evaluation. EPA may not in a risk management rule under section 6(a) regulate non-TSCA uses. TSCA §6(a) generally provides that if EPA determines 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 Agency must apply certain regulatory requirements to the extent necessary so that the chemical substance or mixture no longer presents such risk. The potential risks of non-TSCA uses may help inform the Agency's risk determination for the exposures from uses that are covered under TSCA (e.g., as background exposures that would be accounted for, should EPA decide to evaluate aggregate exposures).

G. Process and Criteria for Manufacturer Requested Risk Evaluations.

TSCA allows a manufacturer or group of manufacturers to request that the Agency

conduct a risk evaluation of a chemical substance (or group of substances) that they manufacture. The statute further directs EPA to establish the "form…manner and…criteria" for such requests as part of this rule.

1. Scope of request. In the proposed rule, EPA required the manufacturers submitting the request to include all information necessary to conduct a risk evaluation on all conditions of use. EPA received numerous public comments on this provision. EPA did receive comments that supported the proposed approach, indicating that the approach was consistent with EPA's own process for evaluating high priority chemicals, and because the chemicals evaluated as the result of a manufacturer request will have not gone through the Prioritization process, where the bulk of information may be gathered, it was appropriate to have manufacturers submit all information necessary to conduct a risk evaluation for all conditions of use. Those opposed to the proposed approach stated that manufacturers are not always privy to every downstream use, and therefore would find it very difficult to obtain all the required information. Commenters also expressed concern that the bar set in the proposed rule overall was too high and would make it extremely difficult for manufacturers to submit a compliant request, and that the extensive requirements EPA had proposed could create a disincentive to submit requests for risk evaluation.

EPA agrees with many of these concerns in opposition to the proposed approach. EPA believes that Congress intended for EPA to establish a process under which the 25%-50% target would most likely be met. The law instructs EPA to "ensure" that that target is met. Section 6(b)(4)(E)(i). While this is conditioned on EPA's receipt of a sufficient number of compliant requests, EPA believes it signals an intent that the criteria for requests make it reasonably likely that the target will be met. Legislative history supports this reading.

See S3516 (June 7, 2016) ("The Administrator should set up a system to ensure that those percentages are met and not exceeded in each fiscal year.")

Upon consideration of these comments, among others, EPA is modifying its proposal in several ways. First, the final rule allows manufacturers to submit requests for risk evaluation on only the conditions of use of the chemical substances that are of interest to the manufacturer.

Although manufacturers may request that EPA conduct a risk evaluation based on a subset of the conditions of use, EPA intends to conduct the risk evaluation in the same manner as any other risk evaluation conducted under section 6(b)(4)(A). This is clear from subsections (A) and (C), and from section 6(b)(4)(E)(ii), which expressly directs that the Administrator shall not expedite or otherwise provide special treatment to manufacturer-requested risk evaluations. As such, EPA intends to conduct a full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that EPA identifies, just as EPA would if EPA had determined the chemical to be high priority. However, rather than require the manufacturer to identify any additional conditions of use that EPA will evaluate, EPA will determine the additional conditions of use during the process of determining whether to grant or deny the manufacturer request. From receipt of a compliant request to initiation of a risk evaluation EPA anticipates 195 days. This includes: (1) public notification of request within 15 days of receipt; (2) Within 60 days after receipt of the request, EPA will publish the request in the Federal Register; (3) EPA will open a docket to facilitate a no less than 45-day public comment period; (4) Within 60 days of the end of the comment period EPA will issue the decision to grant or deny the request; (5) Upon a decision to grant a request, the requester has

30 days to withdraw the request or EPA will move to initiate the risk evaluation.

Upon receipt of a request, EPA will evaluate whether the circumstances of manufacture, processing, distribution in commerce, use, and/or disposal identified by the submitter constitute conditions of use that warrant risk evaluation and whether additional conditions of use need to be included in the risk evaluation. EPA will apply the same criteria in the same manner outlined earlier in this preamble in making these evaluations.

EPA must complete the full risk evaluation that encompasses both the conditions of use that formed the basis for the manufacturer request, and any additional conditions of use that the Administrator determines under section 15 U.S.C. 2605(b)(4)(A), within the statutory three-year deadline. However, as discussed elsewhere in this preamble, EPA may make an early risk determination on any condition of use included in the Agency's scope, after peer review of the risk evaluation for that condition of use. Thus, since manufacturers are required to submit all of the information necessary to complete risk evaluation for the identified conditions of use, EPA expects these conditions of use may be good candidates for an early determination.

2. Information that must be submitted as part of request. Consistent with the proposal, a request must include the chemical identity– all known names, CAS number, and molecular structure. Manufacturers may also submit requests for categories of chemical substances, and such requests must include an explanation of why the category is appropriate under 15 U.S.C. 2625(c). EPA will grant such request only upon determining that the requested category is appropriate for risk evaluation. As described above, manufacturers may now request a risk evaluation based on a subset of conditions of use. The manufacturer's request must include all of the information necessary for EPA to conduct the

evaluation for the requested conditions of use, consistent with the requirements in sections 15 U.S.C 2605(b)(4)(A), and 15 U.S.C 2625(h). This includes all of the necessary information, as relevant to the requested conditions of use, on the chemical substance's hazard and exposure potential; the chemical substance's persistence and bioaccumulation; any relevant potentially exposed or susceptible subpopulation; whether there is any storage of the chemical substance near significant sources of drinking water, including the storage facility location and nearby drinking source; the chemical substance's production volume or significant changes in production volume; and any other information relevant to the risks potentially presented by the chemical substance. The requesting manufacturer does not need to supply a copy of the information if it is publicly available, but must list all references. These are the same requirements EPA listed in the proposed rule; however, the scope of the request may be narrower, specifically regarding the conditions of use requested. Some comments argued that it would be exceedingly difficult to obtain information for uses that the requesting manufacturer may have no knowledge of. EPA agrees with that, and that is a large part of the motivation behind EPA's decision to allow manufacturers to request risk evaluations on limited conditions of use. However, for those conditions of use requested, the manufacturer must provide all the information EPA needs for risk evaluation.

Any information submitted by a manufacturer must be consistent with the scientific standards in 15 U.S.C. 2625(h). Although the judgement of consistency is ultimately EPA's, holding the requester to the statutory standard helps to ensure that if EPA grants the request, the Agency can effectively utilize the information provided. Additionally, any information submitted that is claimed as CBI must be accompanied by a redacted version of the information, including as necessary an accession number and a structurally descriptive

generic name. Instructions for submitting CBI are also included in this rule. Consistent with EPA's general interpretation of section 14, the rule requires upfront substantiation of non-exempt CBI claims.

The final rule also includes a number of other revisions to the information that must be submitted for the request to be considered. In the proposed rule, EPA required manufacturers to submit in the request any risk assessment or evaluation that they might possess. This was added to the proposed rule to provide the Agency with additional information, specifically, as it relates to the hazard assessment. The Agency's intent was to use this as purely another source of information, not base any decision solely on the information in this document. Commenters argued that these risk assessments or evaluations may have been conducted under a different statute or for a particular purpose, and therefore may not be useful or appropriate under TSCA. Additionally, commenters stated that a risk evaluation may have been conducted in response to litigation and therefore would be protected under attorney client privilege. In response to public comments, EPA is removing the requirement that the manufacturer must commit to providing EPA existing risk assessments on the chemical. EPA believes that all relevant risk assessments would be required to be provided pursuant to TSCA section 8(e), and/or would be submitted in response to the regulatory provision that requires that the requesters provide any information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

Many commenters also requested that EPA rephrase the certification statement. Commenters stated that the content of the certification was overly aggressive and unnecessary given the enforcement provision at the beginning of the regulation and the

enforcement that applies to all of TSCA.

3. *Process for evaluating requests*. Upon receipt of the request, EPA will verify that the request appears to be valid, i.e., that information has been submitted that is consistent with the regulatory requirements. Within 15 business days of receiving a facially valid request, EPA will publish a public notice of the receipt, which will include the manufacturer request. This notice is intended to give the public early notice of the chemical substance that may be under evaluation from a manufacturer request. Due to the 15 day turn around on this public notice this will not be a Federal Register Notice, but an announcement on the Agency's website and/or an email announcement. Between receipt of the request and the subsequent end of public comment period (discussed in this next part), EPA will work to identify any additional conditions of use, if any, of the chemical requested. Within 60 days from receipt, EPA will submit for publication an announcement of the receipt of the request in the **Federal Register**, open a docket for the request, make available the information that has been submitted (taking into account any valid CBI claims), and provide no less than a 45-day comment period. This notice will include the manufacturer request and EPA's proposed determinations as to whether the activities identified in the request are conditions of use that warrant risk evaluation, and whether there are additional conditions of use that need to be included in the risk evaluation. This public comment period will allow the public to comment on EPA's proposed determinations and to identify and/or submit any reasonably available information regarding hazard, exposure, potentially exposed populations and subpopulations, and conditions of use that may help inform a risk evaluation. The requesting manufacturer may also submit any additional material during this time.

Chemical substances that EPA has prioritized through the prioritization process (the

subject of separate rulemaking (EPA-HQ-OPPT-2016-0636)), are subject to two separate public comment periods prior to the completion of the prioritization process. These comment periods are designed to ensure that EPA has the necessary information to evaluate the chemical substances, including, in particular, information on the relevant conditions of use. EPA is adopting the similar structure described here for manufacturer requests, under which EPA will solicit input from the public prior to the decision on whether to grant the request, as part of the method by which EPA will identify and gather information on the additional conditions of use to be addressed in the final risk evaluation. Since manufacturers are required to submit all the information necessary to complete risk evaluation on the identified conditions of use, EPA generally expects that the submitted information would include reasonably complete toxicity information on the chemical, even though it would likely not include exposure information relevant to the other conditions of use. While this pre-risk evaluation process for manufacturer request differs from the process of high-priority substances and compresses the period in which EPA will identify conditions of use and supporting information, EPA believes that some differences are necessary in order to effectuate Congress' intent to create a workable process for manufacturer requests that is reasonably likely to hit the numerical target in the statute. Through this mechanism, EPA expects that in many cases, the available information will be comparable to what EPA will identify or generate through the measures identified in the prioritization framework rule. During the public comment period associated with each manufacturer request, EPA encourages public commenters to identify additional information to inform a risk evaluation that was not in the manufacturer request, including any additional conditions of use.

At any time prior to the end of the comment period, the manufacturer may

supplement the original request with new information they receive or obtain. At any point prior to the completion of a risk evaluation conducted on a chemical substance at the request of a manufacturer(s), manufacturer(s) are required to supplement the original request upon receipt of information that meets the criteria in 15 U.S.C. 2607(e) and 40 CFR 702.37, or other information that has the potential to change EPA's risk evaluation for the requested conditions of use.

Within 60 days after the end of the comment period, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the regulatory criteria and will notify the manufacturer(s) accordingly. If EPA determines that the request is compliant (i.e., that the activities for which risk evaluation is requested constitute "conditions of use" as EPA interprets the term, and are conditions of use that EPA concludes warrant inclusion in the scope of a risk evaluation for the chemical, and that EPA has the required information necessary for conducting a risk evaluation on the condition(s) of use requested), EPA will grant the request. Otherwise, EPA will deny the request. Requesters may resubmit any denied request. Within 30 days of the notice that EPA will grant the request, the requestor may withdraw the request for any other reason after the Agency has notified the requester of the decision to grant or deny. For EPA to proceed with a risk evaluation on the chemical requested, it would have to go through the Prioritization process. The process for conducting the risk evaluation will follow the regulatory requirements applicable to high-priority chemical risk evaluations and will not be expedited or otherwise afforded special treatment. EPA will initiate the risk evaluation consistent with TSCA section 6(b)(4)(E)(i) upon payment of required fees requirements as established in the Fees Rule. EPA is not addressing in this rulemaking the fee amount for

manufacturer requested evaluations. The fee amount will be addressed in a separate rulemaking process.

Consistent with TSCA section 6(b)(4)(E)(iii), EPA will give preference to requests where there is evidence that restrictions imposed by one or more States have the potential to have a significant impact on interstate commerce or health or the environment, and is therefore proposing to allow (but not require) manufacturers to include any evidence to support such a finding. Following this required initial preference, EPA will give further preference to requests in the order in which a request is received. This last provision regarding preference is a change from the proposed rule, where EPA indicated that preference would be given to chemicals where EPA determined that there were relatively high estimates of hazard and/or exposure for the chemical substance. EPA received a number of comments arguing that this was not an appropriate way to order chemicals to be evaluated. First, comments asked for a definition of "high estimates of hazard or exposure." Other commenters suggested that manufacturers may submit a request for a low hazard or exposure chemical to get the EPA determination of no unreasonable risk. There were also a few comments that stated that the proposed preference scheme was appropriate in addressing the worst chemicals first. While EPA agrees that this is the best way to approach the identification of high priority substances, EPA does not believe this is necessarily the best approach for selecting among manufacturer-requested evaluations. EPA believes, on reflection, that Congress intentionally established the process for industry requests, to operate outside of the prioritization process, under which lower risk chemicals might be identified for risk evaluation. Therefore, EPA has dropped this proposed preference. EPA also acknowledges it is possible that manufacturers could request an evaluation seeking to get an

Agency determination of no unreasonable risk.

H. Interagency Collaboration.

In the proposed rule, EPA committed to ensuring there will be interagency engagement and dialogue throughout its risk evaluation process; however, EPA chose not the limit the potential interagency collaboration by proposing to codify any particular process. EPA requested specific public comment on whether codifying this collaboration at a specific point regulation was appropriate. Overwhelmingly, commenters were supportive of collaboration with other agencies, and some comments encouraged additional collaboration with state and local agencies, global partners, and tribes. There were mixed comments regarding the codification of interagency collaboration at a particular point in the risk evaluation process. Those in support of the collaboration stated that other agencies, such as the Occupational Safety and Health Administration (OSHA) and the National Institute of Occupational Safety and Health (NIOSH), may have additional information on worker exposure that will undoubtedly be useful for EPA in conducting the risk evaluation. Those opposing the codification argued that this would be overly bureaucratic and a waste of resources, as not all agencies would have an interest/information on every chemical so there would not always be the necessity to consult with them.

EPA has codified collaboration to give the public confidence that EPA will work with other agencies to gain appropriate information on chemical substances. As stated a number of times in this preamble, EPA is committed to transparency and communication with the public. Codification of interagency collaboration is just one more example of this commitment. Through this interagency process, EPA expects to gain additional information into uses and exposure scenarios, with which other agencies may be more familiar.

Additionally, during interagency meetings (under the Office of Management and Budget process of reviewing the proposed rule), other federal agencies expressed significant interest in early and frequent collaboration. Agencies such as NIOSH and OSHA have resources available and information for assessing exposure to workers that EPA may not have. Communication with the Small Business Administration (SBA) Office of Advocacy was requested by a number of commenters. Collaboration with Consumer Product Safety Commission (CPSC), which some commenters argued will be necessary, was requested as EPA evaluates chemicals commonly found in consumer products. There are a number of other agencies that have information and expertise that will undoubtedly be useful to the EPA, and codified collaboration, along with mechanisms already in place, further guarantees that this information will be utilized.

By mandating consultation at any particular stage, EPA does not intend to imply that collaboration with agencies will solely occur at this step of the process, but including this collaboration upon initiation gives other agencies sufficient time to work with the EPA to identify any information that will be useful for EPA risk evaluation (e.g., existing regulations or mission critical uses) of the chemical substance. EPA anticipates that this collaboration would include agencies that may also regulate the chemical substance or the environment in which the chemical substance may be present, as well as agencies that may have critical operations that require the chemical being evaluated, or may otherwise be affected by regulation of the chemical substance. EPA will also consult with the SBA Office of Advocacy and other federal agencies, as appropriate, to help facilitate outreach to the small business sector.

This provision also is not intended to suggest that EPA will not collaborate with

federal agencies prior to the initiation of the risk evaluation. EPA has a number of existing mechanisms already in place to facilitate collaboration between EPA's federal partners and will continue to utilize them. Collaboration with other agencies is an important step in identifying chemicals prior to prioritization, as well as during the risk management phase, if a chemical use is determined to present an unreasonable risk.

As requested in the comments, EPA also plans to engage with state and local agencies where they may have information to inform risk evaluations. Similarly, EPA looks to increase collaboration with tribes, as they can be impacted by chemical substances differently due to unique traditional activities and lifestyles, as discussed in comments.

H. Risk Evaluation Requirements.

1. Considerations. This subpart identifies and discusses what EPA will consider in conducting a risk evaluation. The first subpart identifies the necessary components of the risk evaluation process – a scope, which will include a Conceptual Model and Analysis Plan, a hazard assessment, an exposure assessment, a risk characterization, and a risk determination.

a. Agency guidance. EPA has a number of existing guidance documents that inform Agency risk assessment. EPA has been using risk assessments as a tool to characterize the nature and magnitude of health risks to humans and ecological receptors from chemical contaminants and other stressors that may be present in the environment since its inception. Over the years, EPA has worked with the scientific community and other stakeholders to develop a variety of guidance, guidelines, methods and models for use in conducting different kinds of assessments. A compendium of existing Agency guidance related to risk assessments is maintained on EPA's website (Ref. 15). Additionally, on EPA's website is a

compendium of guidance, databases and models used for assessing pesticide risks (Ref. 16) and information about available predictive models and tools for assessing chemicals under TSCA (Ref. 17). Each of these websites identify and link to a number of written guidance documents, tools and models.

In the proposed rule, EPA made it clear that the Agency would be taking advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. Since each risk evaluation is based on the specific circumstances surrounding the chemical being assessed, EPA did not propose to mandate the use any specific guidance, method or model, to ensure that there is flexibility. EPA asked for comments about this approach.

The majority of the commenters did not think the Agency should mandate the use of or otherwise codify a list of guidance documents. Many public comments mentioned that many of the guidance documents were potentially outdated and were in need of updates. These commenters asserted that codifying these outdated documents would not be appropriate, nor accurately indicate to the public how risk evaluations will be conducted. Additionally, many commenters pointed out the provision in section 26(l) of TSCA that requires EPA to develop and to regularly review and update, the necessary policies, procedures, and guidance. This cuts against mandating use of particular guidance documents in regulation. Other commenters expressed concern that existing guidance did not take into account new science requirements in TSCA. By contrast, some expressed the view that the list should be codified, as it would result in added transparency to the process.

EPA is not codifying a list of guidance (with the exception of the Metals Framework as mandated by TSCA), but states in the regulation that guidance may be used if it constitutes

the best available science, and consistent with the weight of the scientific evidence. This approach is consistent with the proposed rule, and in line with the majority of the comments received on this subject. Rather than starting anew, EPA intends to take advantage of existing guidance, tools and models that are relevant and available for use in conducting a risk evaluation under this program. EPA added a new clause regarding the use of best available science and weight of the scientific evidence to the regulation; this addition of the clause regarding the use of best available science and weight of the scientific evidence was done to ensure that while the documents may have been developed under another statute, EPA will take care to ensure their use would be compliant with the various requirements of section 26 of TSCA. While EPA does think many of the current guidance documents can be utilized effectively under the statute, the Agency agrees with many of the comments that it will be necessary to modify some documents to further adhere to the amendments in the statute, as well as to reflect changing science and technology. Additionally, section 26(l) requires the development of any policies, procedures, and guidance that may be necessary to carry out the amendments of the law, and to routinely review and revise them as necessary to reflect scientific developments. Codifying documents that may be changed, while not codifying others that have yet to be developed, could potentially lead to long processes to change the rule language.

The scope of each risk evaluation will identify those guidance documents that the Agency expects to utilize to inform the risk evaluation. EPA will use the guidance only to the degree that it represents the best available science appropriate for the particular risk evaluation. EPA recognizes that some guidance may be outdated and may rely on defaults where no data exists currently to replace those defaults.

b. Categories of chemical substances. TSCA provides EPA with authority to take action on categories of chemical substances: groups of chemical substances which are, for example, similar in molecular structure, in physical, chemical, or biological properties, in use, or in mode of entrance into the human body or into the environment. Although the rule most often references "chemical substances," EPA includes a clear statement in the final regulation that nothing in the rule shall be construed as a limitation on EPA's authority to take action with respect to categories of chemical substances, and that, where appropriate, EPA can evaluate categories of chemical substances. This is the same provision that EPA included in the proposal, but EPA has removed the statement regarding the Agency's consideration of hazards and exposures associated with the category of chemicals, and the populations likely exposed. EPA believed that this was duplicative, because EPA is required to treat categories of chemicals in the same manner as individual chemical substances.

c. Science requirements. EPA has incorporated into the regulatory text the statutory requirements regarding best available science and weight of the scientific evidence. Definitions of those terms have also been added. While EPA prefers high quality data, where available, EPA recognizes that data is not always necessary to reach a scientifically grounded conclusion on the potential risks of a chemical substance, within the timeframes dictated by the statute.

As a matter of practice, EPA has been, and will continue to be, committed to basing its decisions on the best available science and the weight of the scientific evidence. In response to public comments on the proposal, EPA has determined to make a number of additions to the final rule to ensure that the science standards in TSCA are more explicitly incorporated into the risk evaluation process. Specifically, EPA has added specific language

to the final rule stating that EPA will evaluate hazard and exposure data in a manner consistent with the section 26 science standards including documenting the use of the standards in 15 U.S.C. 2625(h) and the weight of the scientific evidence in 15 U.S.C. 2625(i). These changes clarify that EPA's risk evaluations will be consistent with TSCA's new requirements in section 26 related to best available science and weight of the scientific evidence.

d. Fit-for-purpose risk evaluations. As described in the proposed rule and in Unit III.D.10, each risk evaluation will be fit-for-purpose – that is to say, the level of refinement will vary as necessary to determine whether the chemical substance presents an unreasonable risk, given the nature of the evidence, for the conditions of use of a specific chemical substance. A number of the public comments received stated their support for this approach, as it conserves the Agency's resources to focus on the most important components of a given risk evaluation.

EPA introduced the idea that risk evaluations would be conducted in a fit-for-purpose manner in the proposed rule. Specifically, EPA stated that all conditions of use evaluated will not warrant the same level of evaluation, and that EPA expects, that in some cases, it may be able to reach conclusions without extensive or quantitative evaluations of risk. For example, a lower-volume or less dispersive (those uses that do not spread as far in the environment, either indoors or outdoors as compared to a different use) condition of use might require a less quantitative, data-driven evaluations to credibly characterize the risks than uses with more extensive or complicated exposure patterns. Consistent with EPA's current practice in conducting risk assessments, technically sound risk determinations can be made, consistent with the best available science, through a combination of different types of

information and methods approaches. EPA will continue to utilize this approach and has retained it in the final rule. The concept of fit-for-purpose risk evaluations is further explained in the regulation as follows: EPA will refine, as necessary, its evaluations for one or more conditions of use in any risk evaluation and when information and analysis are sufficient to make a risk determination using assumptions, uncertainty factors, and models or screening methodologies, EPA may decide not to refine its analysis further. Both of these provisions give EPA the flexibility to conduct risk evaluations in a manner that best suits the available information and the decisions that will be made. These are generally consistent with the proposed text, however some changes have been made, namely the exclusion of the phrase "accepted science policies." A number of commenters expressed concern regarding the lack of clarity of this language. Commenters asked for specific examples of science policies and some commenters expressed concern that the Agency would confuse science with regulatory policy, and specifically encouraged separation between the two, to ensure that EPA's decisions would be science-based. To address these concerns EPA has deleted the reference to "science policies" from the rule text.

Many commenters suggested that this fit-for-purpose approach would be necessary to evaluate chemical substances within the statutory timeframe, and agreed that this is appropriate because due to the nature of some uses, some will not necessitate the same level of evaluation as others. By contrast, some commenters were concerned that the fit-for-purpose approach is not scientifically sound and can never be objective. To clarify, EPA will not sacrifice best available science in implementing this approach. The speed of an evaluation does not equate to less rigorous science. EPA will always be transparent about the data and assumptions used.

e. *Timing of a risk determinations.* In the proposed rule, EPA explicitly allowed for the expedited evaluation for a particular condition of use to, if necessary, move more rapidly to risk management under TSCA section 6(a) (15 U.S.C. 2605(a). This could include a situation in which a single use presented an unreasonable risk of injury for the population as a whole or for a susceptible subpopulation (e.g., one use results in risks that EPA would determine unreasonable regardless of the risk posed by other uses). A number of commenters raised concern about the apparent one-sided nature of this provision, arguing that this appeared to preclude a similar determination that a chemical substance did not present an unreasonable risk. EPA agrees that logically such determinations could be appropriate in either case, and has revised its approach to apply more generally. Accordingly, the final regulation at 720.41(a)(7) has been revised to clarify that EPA may make early risk determinations that a chemical substance does or does not present an unreasonable risk under particular conditions of use. The final rule also makes clear that any expedited determination may be issued at any point after the final scope is published. As discussed previously, all early determinations would be portions of the final, complete risk evaluation and would therefore be made using the procedures applicable to TSCA risk evaluations established in this rule. TSCA is very clear that unreasonable risk determinations cannot be made until after a risk evaluation that meets the requirements of section 6(b)(4) is complete. Any risk evaluation for a chemical under particular conditions of use will therefore be consistent with all statutory requirements as well as the procedures established in this regulation. This would also include the requirement that EPA publish a draft risk evaluation for no less than a 60-day public comment period, and the regulatory requirement for peer review.

The final regulation also continues to explicitly state that in any case where EPA

would find it necessary to issue an early risk determination for a chemical substance under particular conditions of use of a chemical, the Agency will still complete a risk evaluation on all conditions of use identified in the final scope, within the statutory 3-year deadline. In sum, the final rule explicitly recognizes that EPA may make early risk determinations, to either to manage unreasonable risks as they are identified, through the issuance of a regulation under TSCA section 6(a) or to notify the public as soon as possible of the safety of a chemical substance under a particular condition of use.

f. Metals or metal compounds. As required by the statute, when evaluating metals or metal compounds, EPA must use the March 2007 Framework for Metals Risk Assessment of the Office of the Science Advisor (Ref. 3) or a successor document that addresses metals risk assessment and is peer- reviewed by the Science Advisory Board. The final rule, consistent with the proposal, merely reiterates this statutory mandate.

2. Information and information sources. For those chemical substances designated as high priority for risk evaluation, EPA expects to initiate the process when EPA has determined that most of the information necessary to complete the evaluation is reasonably available, which in most cases means the information already exists. In the proposal, EPA had stated that the goal would be to "only" initiate the process once most of the information necessary to complete the evaluation was reasonably available. In the final rule the word "only" has been deleted to account for the fact that EPA may use its regulatory authorities to obtain or require the generation of additional information even after the risk evaluation has been initiated.

For manufacturer requested risk evaluations, EPA acknowledges it may potentially be difficult to gather all of the necessary information prior to risk evaluation, as these

chemicals will not have gone through the prioritization process. Nevertheless, EPA generally expects that it will be feasible to obtain the necessary information to complete a risk evaluation within the statutory timeframe. As discussed previously, the final rule requires a manufacturer to submit all of the necessary hazard information for EPA to complete a risk evaluation on the one or more conditions of use that have been requested. Although there may be other hazards associated with other conditions of use that present different routes of exposure, EPA expects that the majority of the necessary hazard information will be obtained through the request. EPA has then allotted 195 days from receipt of request to gather additional information required to assess both requested uses and any additional conditions of use EPA has determined warrant evaluation. For both EPA- and manufacturer-initiated risk evaluations, EPA may also rely on information developed through the use of novel and advancing chemical assessment procedures, measures, methods, protocols, methodologies, or models (e.g., high-throughput chemical assessment techniques).

For identified data needs, EPA may issue a voluntary call to the public for relevant information or otherwise engage directly with stakeholders, followed, as necessary, by exercise of EPA's authorities under TSCA to require submission or generation of new data. Accordingly, as appropriate, EPA will exercise its TSCA information collection, testing, and subpoena authorities, including those under TSCA sections 4, 8, and 11(c) to obtain the information needed for a risk evaluation. EPA notes as well that TSCA section 8(e) requires that any person who manufacturers, processes, or distributes in commerce a chemical substance or mixture and who obtains information which supports the conclusion that this substance or mixture presents a substantial risk of injury to health or the environment, shall immediately inform the Agency, and EPA may obtain some information through this route.

EPA also expects to obtain scientific advice from the Science Advisory Committee on Chemicals (SACC), which the Agency is required to develop and convene under TSCA section 26(o).

When conducting a risk evaluation, EPA will ensure that risk evaluations are consistent with the scientific standards in section 26(h) and (i), including reliance on the best available science and the weight of the scientific evidence. EPA will rely on data, models, and screening methods, as needed. The use of these methods will be balanced by the quality of the information (consistent with standards in section 26(h) and (i)) and the statutory deadlines for completing a risk evaluation. In the final rule, EPA will use the scope to focus on the reasonably available information and science approaches, and reserve uncertainty considerations specifically for the remainder of the risk evaluation.

EPA does not intend to preclude the generation of new scientific information to inform risk evaluations, however, as mentioned in the discussion of reasonably available information, the extent to which EPA will consider any newly generated information in a risk evaluation will depend on the statutory deadlines.

In compliance with the statute, EPA will work to reduce and replace, to the extent practicable, the use of vertebrate animals in testing chemical substances as outlined in TSCA section 4(h). The intent to reduce testing on animals was in the proposed text, however comments suggested the language was not exactly as the statute intended, and that it should refer to the development of new information, not all existing information, as it could have been interpreted. The final rule text has been amended to more closely hew to the statute.

I. Risk Evaluation Steps.

1. Scope. The first step of a risk evaluation is the development of the scope. The

scope of each risk evaluation will include the following components. The conditions of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation will be included in the scope. This is amended from the proposed rule to address the approach to conditions of use as explained in Unit III.B. The EPA will identify the potentially exposed or susceptible subpopulations EPA expects to consider, the ecological receptors, and the hazards to human health and the environment the Agency plans to evaluate will also be included. From the proposed rule, EPA changed "ecological characteristics" to "ecological receptors." This was done to clarify that the Agency will be evaluating specifically the impact of the chemical stressor, and EPA believes that characteristics was too broad, and receptors more closely hew a chemical risk assessment. The scope will include a description of the reasonably available information and the science approaches that the Agency plans to use. In the proposed rule EPA had included that the reasonably available information would include "accepted science policies (e.g., defaults and uncertainty factors), models, and screening methodologies." As already discussed, a number of commenters expressed their concern with this language and in response EPA removed this provision. Under the final rule, the scope will focus on the reasonably available information and science approaches, and reserve uncertainty considerations specifically for the remainder of the risk evaluation.

EPA will include a conceptual model that will describe the actual or predicted relationships between the chemical substance and the receptors, either human or environmental, with consideration of potential hazards throughout the life cycle of the chemical substance – from manufacturing, processing, distribution in commerce, storage, use, to release or disposal.

Also included will be an analysis plan, which will identify the approaches and

methods EPA plans to use to assess exposure, hazards, which will include dose-response, and risk, including associated uncertainty and variability. The analysis plan will also include a description of the reasonably available information and science approaches the EPA plans to use.

As requested by a number of commenters, the scope will also include the plan for peer review the Agency expects to consider. This may include the plan for peer review for those conditions of use that EPA expects to make early risk determinations on. This plan may also include the Agency's plan to have any methods or models peer reviewed, along with the risk evaluation, as well as the EPA's anticipated use of the SACC or another peer review body or whether the Agency anticipates a letter peer review or a committee consensus peer review. The Peer Review Handbook walks through the numerous options the Agency can use, and the plan will give the public an idea of what the Agency intends to use for a particular risk evaluation."

EPA will publish a notice in the **Federal Register**, announcing the availability of the final scope within six months of the initiation of the risk evaluation. Although not required under the statute, EPA will publish a draft scope and provide for no less than a 45 calendar day public comment period during this six-month period. As a number of commenters pointed out, there was a mistake in the proposed rule – the length of the commenter period on the draft scope was 30 days in the preamble, but 45 days in the regulatory text. EPA has corrected this mistake. EPA welcomes all public participation, but specifically encourages commenters to provide information they believe might be missing or may further inform the risk evaluation. That said, the prioritization process requires two public comment

opportunities, and EPA expects this will reduce the likelihood of significant comments on the draft scope for those High-priority chemicals.

EPA has deleted the issue preclusion clause included in the proposed rule stating that "any issues related to the scope not raised in the comments at that time cannot form the basis for an objection or challenge in a future administrative or judicial hearing" in response to a significant number of comments. However, under general principles of administrative law, commenters are required to identify relevant available information and raise objections that could be raised during established comment periods, and courts generally will require commenters to have done so as a matter of exhaustion of administrative remedies. EPA has concluded that these principles provide sufficient assurance that commenters will raise timely objections and provide timely information and has therefore decided to strike the proposed regulatory text.

2. Hazard assessment. In compliance with TSCA section 6(b)(4)(F), EPA will conduct a hazard assessment on each chemical substance or category, under the conditions of use as identified in the scope. A hazard assessment identifies the types of adverse health or environmental effects or hazards that can be caused by exposure to the chemical substance in question, and to characterize the quality and weight of the scientific evidence supporting this identification. Hazard identification is the process of determining whether exposure to a chemical stressor can cause an increase in the incidence of specific adverse health or environmental effects (e.g., cancer, developmental toxicity). All information used in this assessment will be reviewed in a manner consistent with reliance on the best available science and a weight of the scientific evidence approach.

As the rule text indicates, EPA will present the hazard information, as identified in the scope, for the identified exposure scenarios, and including any identified potentially exposed or susceptible subpopulation. From the proposed rule, EPA changed the word "endpoints" to "hazards," as hazards is more general and inclusive.

The hazard assessment will identify the types of hazards to human health and the environment. The information will be reviewed in a manner consistent with use of the best available science and with the weight of scientific evidence. This will include the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical, under the conditions of use, and all assessment methods will be documented. This hazard assessment may include, but may not be limited to, evaluation of the potential toxicity of the chemical substance with respect to cancer, mutation, reproductive, developmental, respiratory, immune, and cardiovascular impacts, and neurological impairments. The assessment may evaluate effects at life stage(s) most appropriate for a receptor target.

A hazard assessment also will include a dose-response assessment. A dose-response relationship describes how the likelihood and severity of adverse health effects (the responses) are related to the amount and condition of exposure to an agent (the dose provided). The same principles generally apply for studies where the exposure is to a concentration of the agent (e.g., airborne concentrations applied in inhalation exposure studies or water or other media concentrations for ecological exposure studies), and the resulting information is referred to as the concentration-response.

Potential information sources that may support the hazard assessment include but are not limited to: population based epidemiological studies that identify risk factors and

susceptible subpopulations; information related to geographic location of subpopulations; models that represent health effects of relevant subpopulation; *in vivo* and/or *in vitro* laboratory studies; mechanistic or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, and computational toxicology, which the final rule makes clear may include high-throughput assays, genomic response assays, data from structure-activity relationships, and ecological field data. The hazard identification will also include an evaluation of the strength, limitations, and uncertainties associated with the reasonably available information. The final rule was amended to include uncertainties as commenters encouraged EPA to further discuss how uncertainties will be addressed in this process.

Specifically, for human health hazards, the assessment will consider all potentially exposed or susceptible subpopulation(s) identified in the scope. EPA will use an appropriate combination, if available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing health effects to the population, and any other information or methodology consistent with scientific standards.

An environmental hazard assessment will evaluate the relationship between the chemical substance and the occurrence of an ecological response. This assessment may be conducted using reasonably available information from field or laboratory data, modeling strategies, and species extrapolations, if needed.

Changes from the proposed rule include the addition of EPA's commitment to using the best available science and a weight of the evidence approach. Some specific details regarding the available information that may be used in hazard assessments have been moved to this preamble. The proposal stated that EPA "may include" followed by a list of types of

information, and although the phrase “may include” provides flexibility, EPA believes that it is more appropriate to not codify this level of specific detail in the regulation. Many public comments encouraged transparency in the Agency’s risk evaluation process, but because this rule must cover the process for all risk evaluations, which by nature will necessitate the consideration of many types of information sources, EPA believes the better (and ultimately more accurate) approach is to ensure that it provides full transparency in the individual risk evaluations.

3. Exposure assessment. Pursuant to TSCA section 6(b)(4)(F), EPA, “where relevant, will take into account the likely duration, intensity, frequency, and number of exposures under the conditions of use in an exposure assessment.” An exposure assessment will include information on chemical-specific factors, including but not limited to: physical-chemical properties and environmental fate and transport parameters. These considerations were included in the proposed rule; however “transport” has been added to the final text. Fate and transport in environmental media are commonly assessed together, and this is more consistent with EPA’s current practices. EPA has also added a statement in the rule text regarding the use of best available science and weight of scientific evidence approaches. As stated elsewhere in the preamble, EPA is committed to upholding these statutory requirements.

An exposure assessment includes some discussion of the size, nature, and types of individuals or populations exposed to the agent, as well as discussion of the uncertainties in this information. Exposure can be measured directly, but when data is unavailable it is estimated indirectly through consideration of measured concentrations in the environment, consideration of models of chemical transport and fate in the environment, and estimates of

human intake or environmental exposure over time. A number of commenters encouraged the use of probabilistic approaches as they provide better estimates of exposure when compared to specific "bright line" approaches. In response EPA will strive to utilize probabilistic approaches for exposure assessments included in a risk evaluation but has not revised the proposed regulation, consistent with its approach to other provisions, where EPA has moved many of the specific approaches that appeared in the proposed rule text into the final preamble. EPA believes that this level of detail regarding the specific information types used in risk evaluation is more appropriate for guidance. Commenters had also suggested that guidance is more appropriate for specific methods and approaches because it can be amended easily to adopt to changing science. Codifying specific methods could unnecessarily restrict the Agency's ability to review all pertinent information.

Using reasonably available information, exposures will be estimated (usually quantitatively) for the identified conditions of use. For human health exposure, the assessment would consider all potentially exposed or susceptible subpopulation(s) identified in the scope and utilize any combination, as available, of population-based epidemiological studies, information related to geographic location of susceptible subpopulations, models representing exposures to the population, measurements in human tissues or relevant environmental or exposure media, and any other relevant, scientifically valid information or methodology. In an environmental health exposure assessment the interaction of the chemical substance with any ecological characteristics identified in the scope will be characterized and evaluated. As with the hazard assessment, specific details on the source of information EPA will use have been moved to this preamble to allow for flexibility in identifying the appropriate sources of information.

4. Risk characterization. TSCA requires that a risk evaluation "integrate and assess available information on hazards and exposures." (15 U.S.C 2605(b)(4)(F). A risk characterization conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made. Risk characterization takes place for both human health risk assessments and ecological risk assessments. The proposed text only included the necessity for EPA to describe whether aggregate or sentinel exposures were considered during the risk evaluation and the basis for that consideration. The final rule text was amended to include all of the statutory requirements of the risk evaluation process, including: not considering costs or other non-risk factors; taking into account the likely duration, intensity, frequency, and number of exposures under the condition(s) of use; and a description of the weight of scientific evidence for the identified hazards and exposures. The statute requires a risk evaluation to include all of these components, so EPA believed it was necessary to codify them all, rather than to single out just one of the requirements.

In the risk characterization summary, EPA will further carry out the obligations under TSCA section 26; for example, by identifying and assessing uncertainty and variability in each step of the risk evaluation, discussing considerations of data quality such as the reliability, relevance and whether the methods utilized were reasonable and consistent, explaining any assumptions used, and discussing information generated from independent peer review. 15 U.S.C. 2625(h). EPA may include a discussion of alternative interpretations, where these interpretations are plausible, of results generated from the risk evaluation. EPA amended the regulation text to include the phrase "where these interpretations are plausible,"

because EPA believes, in agreement with a commenter, that through the use of best available science and weight of scientific evidence approaches, it is feasible that not every risk evaluation will have alternative interpretations. EPA wants to be clear that alternative interpretations will be presented in the risk characterization on a case-by-case basis, but may not be the norm, as requested by another commenter.

For environmental evaluations specifically, EPA plans to include a discussion of the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance. A few commenters suggested that when conducting an ecological risk assessment, it is important to consider the population level, as this was not included in the proposed rule. The commenters' suggestion more accurately reflects EPA's general practices for ecological risk assessments and this change has been made in the final rule.

In practice, each component of the risk assessment (e.g., hazard assessment, dose-response assessment, exposure assessment) has an individual characterization written to carry forward the key findings, assumptions, limitations, and uncertainties. The set of these individual characterizations provide the information basis to write an integrative risk characterization analysis. The final, overall risk characterization thus consists of the individual component characterizations plus an integrative analysis. Each risk evaluation will quantitatively and/or qualitatively estimate and characterize risk for the identified populations and ecological characteristics under the conditions of use.

EPA has historically used a MOE approach in risk characterization of TSCA risk assessments. The proposed rule asked the public to comment on the strengths and

weaknesses of the MOE approach. EPA received many comments with thoughtful reasoning both for and against using this approach. As discussed by commenters, the benefits of the MOE approach include the assertion that the approach is more transparent than other approaches, such as a hazard index or hazard quotient, because the application of uncertainty factors is transparent, and that the MOE approach can incorporate data from multiple pathways and endpoints. Some supporters of the MOE approach did encourage EPA to not prescribe a single value that would be used for all risk evaluations, but to select a MOE value that is fit-for-purpose and specifically associated with the evidence of the evaluation.

Commenters that were not supportive of this approach expressed their concern for this "bright line" approach, in that it does not reflect knowledge about what the potential risks are above or below the 'line,' and that it assumes a safe level of exposure below which harm will not occur. Others commented that the MOE approach is not always easily communicated to the public. Many commenters suggested alternatives, including the use of probabilistic approaches, arguing that they better account for variability and uncertainty. Finally, others commented that it was not appropriate to call out specific methods, as this is more appropriate for guidance.

Agreeing with the consensus from the comments, EPA acknowledges that MOE is just one of many ways to characterize risk. There will be risk scenarios where one approach may be better than another, and as commenters correctly pointed out, the science of risk characterization is still evolving, particularly for non-cancer hazards. To account for the number of different approaches and for changing science, EPA will not codify any specific method in this final rule.

Finally, EPA will utilize EPA's Information Quality Guidelines in the risk

characterization section of the risk evaluation, as it provides guidance for presenting risk information (Ref. 5). As explained in that document, EPA should identify: (1) each population addressed by an estimate of applicable risk effects; (2) the expected risk or central estimate of risk for the potentially exposed or susceptible subpopulations affected; (3) each appropriate upper-bound or lower-bound estimate of risk; (4) each significant uncertainty identified in the process of the assessment of risk effects and the studies that would assist in resolving the uncertainty; and (5) peer-reviewed studies known to the Agency that support, are directly relevant to, or fail to support any estimate of risk effects and the methodology used to reconcile inconsistencies in the scientific information.

5. Peer review. For each risk evaluation conducted on chemicals identified pursuant to TSCA section 6(b)(4)(A), EPA will conduct a peer review using the guidance provided in executive branch peer review directives, including in the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin) (Ref. 18) and in the EPA Peer Review Handbook (2015) (Ref. 19) or its updates. For those conditions of use that may receive an early determination of no unreasonable risk, EPA will ensure that the risk assessments underlying these determinations are reviewed in a manner consistent with the OMB Bulletin and the EPA Peer Review Handbook. These documents do provide some latitude for the type of peer review that EPA can conduct, which EPA will take advantage of. For example, in determining the appropriate type of peer review, EPA can consider the complexity of the information and any prior peer review of underlying information. EPA may also utilize the SACC in reviewing the science that underlies these determinations.

As discussed in the proposed rule, EPA will identify aspects of the analysis on which peer review will be conducted, and the planned methodologies, as part of the draft scoping

document that will undergo public comment for each chemical substance that undergoes risk evaluation. These may include novel models or analyses that warrant an in-depth peer review. In addition to any targeted peer review of specific aspects of the analysis, the entire risk assessment will also undergo peer review, as it is important for peer reviewers to consider how the various underlying analyses fit together to produce an integrated risk characterization, which will form the basis of an unreasonable risk determination. A number of commenters argued for involvement of the public into the peer review process. To respond to this, EPA plans to take public comment on the charge questions given to peer reviewers.

The peer review will address aspects of the science underlying the assessment, including, but not limited to hazard assessment, assessment of dose-response, exposure assessment, and risk characterization. Consistent with the proposed rule, EPA will not seek review of any determination as to whether the risks are "unreasonable," which is an Agency policy determination. EPA did receive public comment requesting that the risk determination also be subject to peer review; however, EPA strongly believes that the purpose of peer review is for the independent review of the science underlying the risk assessment, not an evaluation of EPA's policy determinations. TSCA expressly reserves to the Agency the final determination of whether risk posed by a chemical substance is "unreasonable." 15 U.S.C. 2605(i). EPA nevertheless will include its risk determination as part of the risk evaluation that is subject to public review and comment.

EPA specifically requested public comment on whether there are circumstances where conducting peer review may not be warranted, (e.g., what circumstances may require peer review and if there are others that may not) and whether the regulatory text should be

adjusted to require EPA to make a case by case determination of whether and to what extent, consistent with the EPA Peer Review Handbook, peer review is warranted for the chemical substance undergoing a risk evaluation. The comments received were generally very supportive of conducting a peer review on all risk evaluations. There were some comments that encouraged discretion as to whether peer review had to be conducted on a particular risk evaluation (e.g., determinations of no unreasonable risk, or on evaluations were the result was consistent with other national or international conclusions). Commenters also raised issues regarding the timing of peer review in the risk evaluation process (e.g., after public comment), what should and should not be included in peer review (e.g., the risk determination), and views on what type of peer review should be conducted (e.g., full panel review). EPA's responses to specific comments are addressed in the response to comment document.

Accordingly, EPA has retained the provision from the proposed rule requiring peer review on all risk evaluations. Guidance on how peer review will be conducted will remain consistent with the EPA Peer Review Handbook. For clarity, EPA did move the peer review provision to its own section of the rule, as suggested by a commenter. EPA agrees with comments that peer reviewed evaluations will instill greater confidence and provide transparency to the process. EPA postulated in the proposed rule that there may be circumstances that may not necessitate peer review (e.g., where a chemical substance is found to not present an unreasonable risk or that findings are similar or the same as other jurisdictions (states or countries) that have reached similar conclusions based on the same information). Public comment presented arguments to why this is not appropriate. Although a substance may not present an unreasonable risk, the consequence of a 'false negative' could

be extremely problematic. For the second scenario where EPA's results may be similar to another jurisdiction's, commenters argued that it will also be necessary to peer review the evaluation. It would be necessary to make certain the best available science and weight of the scientific evidence approaches were used properly, as they may not have been required under the process by which the comparable evaluation was conducted. As such, EPA will require peer review on all risk evaluations.

6. Unreasonable risk determination. The final step of a risk evaluation is for EPA to determine whether the chemical substance, under the conditions of use, presents an unreasonable risk of injury to health or the environment. EPA will make individual risk determinations for all uses identified in the scope. This part of the regulation is slightly amended from the proposed rule, to clarify that the risk determination is part of the risk evaluation, as well as to account for the revised approach to that ensures each condition of use covered by the risk evaluation receives a risk determination. Due to EPA's decision to allow for early determinations on one or more conditions of use, where appropriate, risk determinations may be published in multiple documents or in a single document containing all risk determinations for all identified uses. If the determinations are published in multiple documents, the final determination will be a composite document of all determinations made. EPA's determinations will specify whether each condition of use identified for a chemical substance does or does not present an unreasonable risk of injury to health or the environment. A determination that a condition of use does not present an unreasonable risk is considered to be a final EPA action. If EPA determines that the chemical substance, under one or more condition of use, does present an unreasonable risk, EPA must initiate a rulemaking pursuant to TSCA section 6(a) to impose requirements to the extent necessary so

that the substance no longer presents such risk. 15 U.S.C. 2605(a). Any rule would apply only to the condition(s) of use that present an unreasonable risk, and those that do not present an unreasonable risk will not be subject to risk management. A number of commenters asked EPA to communicate clearly which uses may go to risk management following the evaluation. EPA will clarify in the draft and final risk evaluation documents specifically which condition(s) of use warrant risk management and which do not.

7. Reassessment of unreasonable risk determination. EPA stated in the proposed rule that it may reassess determinations of unreasonable risk. A number of commenters requested clarification on when and how this might happen. Following review of the comments, EPA has deleted the provision as it was unnecessary. Generally, agencies are authorized to revisit determinations they are charged by statute to make, and nothing in TSCA prevents EPA from doing that. EPA is also concerned that the provision could have been read as an effort to limit, expand, or otherwise alter the statutory authority.

8. Additional publicly available information. Pursuant to TSCA section 26(j), and subject to TSCA section 14, the final regulation specifies that EPA will make available: (1) The draft scope, final scope, draft risk evaluation, and final risk evaluation; (2) All notices, determinations, findings, consent agreements, and orders; (3) Any information required to be provided to the Agency under 15 U.S.C. 2603; (4) A nontechnical summary of the risk evaluation; (5) A list of the studies, with the results of the studies, considered in carrying out each risk evaluation; (6) Each determination as to whether the chemical substance presents an unreasonable risk under one or more conditions of use, along with an identification of the information, analysis, and basis used to make the designation; (7) The final peer review report, including the response to peer review and public comments received during peer

review; and (8) Response to public comments received on the draft scope and the draft risk evaluation. In this final rule there are a few slight changes from the proposed regulation, largely to conform to changes made to other sections of the rule. The final rule now includes number 6, which has been slightly amended from the statute to make clear that EPA will be making public its risk determinations (the statute uses the term "designations"). In addition, the final regulation now specifies and that these determinations will be made for the chemical under the one or more conditions of use identified in the risk evaluation.

IV. Summary of Request for Specific Public Comment on the Proposed Rule

In the Proposed Risk Evaluation Rule, EPA requested specific public input on a number of subjects. These subjects are listed below along with reference of the particular section where EPA has discussed the public comment.

1. *Redefining scientific terms.* Unit III.D.
2. *Margin of Exposure.* Unit III.D.13.
3. *Systematic Review.* Unit III.D.12.
4. *Manufacturer requests.* Unit II.A.2.
5. *Peer Review.* Unit III.G.5.
6. *Reliance on existing guidance and procedures for conducting risk evaluations.* Unit III.G.1.a.
7. *Interagency collaboration.* Unit III.H.

V. Cost Analysis

Industry costs for this rule are limited to activities a manufacturer must perform in order to meet the requirements outlined in previous sections. Manufacturers are not required to submit a chemical substance for risk evaluation, therefore these costs will only be

experienced when a given manufacturer chooses to make a submission to the Agency. The fully loaded wage rate of a technical professional (i.e., toxicologist) of $78.40 was used to calculate the cost of labor burden.

A. Number of Entities Affected

EPA developed estimates for the number of manufacturers who are likely to elect to submit a chemical substance for risk evaluation. Since submissions of this nature have never been collected by the Agency before, the actual number of expected submittals is relatively unknown. However, EPA assumes 5 chemical manufacturers may submit requests to the Agency in any given year. The Agency will not be required to perform 20 risk evaluations at any given time until 2 years after rule finalization. Based on this, assuming 25 percent of total risk evaluations coming from manufacturer submissions was considered a best estimate with the lack of actual data. The total number of entities affected by the recordkeeping and reporting requirements of the rule, therefore, is estimated to be 5 chemical manufacturers per year.

B. Rule Familiarization Burden

EPA assumes that each manufacturer who elects to submit a chemical substance for risk evaluation consideration is assumed to spend one hour becoming familiar with the requirements of the rule and developing an understanding of what actions are necessary to complete the forms and submission package. This is separate from the time it takes to create the submission package itself.

The total cost of rule familiarization is estimated to be $392 per year (5 x 1 x 78.40 = 392).

C. CDX Electronic Reporting Burden

Manufacturers requesting a chemical substance be considered by EPA for risk evaluation are required to provide the submission package to the Agency via the CDX electronic system. While several manufacturers may be familiar with the CDX system and are registered users because the same system is used for new chemical submissions to the Agency (e.g., pre-manufacture notice, significant new use notice, low volume exemptions) there is no way to estimate which manufacturers submitting risk evaluation requests are familiar with CDX and which are new to the system. Therefore, EPA assumes submissions under this rule are performed by new users of CDX which may result in an overestimate of burden.

The CDX electronic reporting burden includes registration to CDX, familiarization with the subscriber agreements, potential use of the help desk, and problem resolution. The burden estimates used in this rule are based off of estimates in EPA ICR No 2502.02, resulting in a burden of 2.83 hours per respondent.

The total cost of CDX electronic reporting burden is estimated to be $1,109 per year (5 x 2.83 x 78.40 = 1,109).

D. Submission Package Burden

Chemical manufacturers electing to request EPA consider a chemical substance for risk evaluation must provide a submission package including the following information: contact information of requesting entity(s), full chemical identity information, complete list of reasonably available information consistent with TSCA section 26(h) standards that is relevant to an unreasonable risk determination, addresses all the circumstances that constitute conditions of use, of interest to the manufacturer, within the meaning of TSCA section 3, contain a commitment to provide EPA any referenced information upon request of the

Agency, and provide a signed certification that all information in the submission is accurate and complete.

While submissions of this nature have never been required or requested by EPA in the past, the Agency has performed similar tasks internally while conducting previous Risk Evaluations. The average contractor expense and labor time the Agency spends on the types of activities required to prepared the submission package covered by this rule were used to develop the burden and cost estimates.

EPA estimates the cost of having a contractor conduct an in-depth literature review and screen the literature found for relevance costs an average of $50,000 per chemical. This includes the cost of using literature review databases and the contractor labor time involved in performing the review and screening activities. In addition to the contractor cost, the manufacturer is expected to spend an average of 80 hours per chemical reviewing the data found during the literature, refining the searches as needed, and preparing the submission package. Therefore, the estimated burden for developing and submitting a risk evaluation request is 80 hours per respondent with an additional direct cost of $50,000 per submission package.

Total cost for submission package burden is estimated to be $281,360 per year (5 x 50,000 x 80 x 78.40 = 281,360).

E. Total Cost

The total annual cost for this rule is estimated to be $282,861 per year (392 + 1,109 + 281,360 = 282,861) under the assumption EPA receives 5 manufacturer requests per year. Manufacturers choosing to submit a chemical substance for risk evaluation may be a small entity. Due to the low cost ($56,572) of a single submission package, the cost of the

voluntary submission is expected to impact less than 1% of the small business at greater than 3% of average revenue in the estimated universe of small businesses.

VI. References

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

1. USEPA. Information Collection Request (ICR) for the Proposed Rule: Procedures for Chemical Risk Evaluation Under TSCA. EPA ICR No.: 2559.01 and OMB No. 2070-[NEW].

2. EPA. TSCA Work Plan Chemical Assessments: 2014 Update-Final. Office of Pollution Prevention and Toxics. October 2014. *https://www.epa.gov/sites/production/files/2015-01/documents/tsca_work_plan_chemicals_2014_update-final.pdf.*

3. EPA. Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum. Washington D.C. March 2007.

4. USEPA. Exposure Factors Handbook. EPA/600/R-090/052F. Office of Research and Development, National Center for Environmental Assessment. Washington, D.C. 2011. *https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=236252.*

5. Guidelines for Ensuring and Maximizing the Quality, Objectivity, Utility, and Integrity of Information Disseminated by the Environmental Protection Agency. EPA/260R-

02-008. Washington, D.C. 2002. *https://www.epa.gov/sites/production/files/2015-08/documents/epa-info-quality-guidelines.pdf.*

6. European Centre for Ecotoxicology and Toxicology of Chemicals (ECETOC). Targeted Risk Assessment User Guide. version 3.1. June 2014. *http://www.ecetoc.org/wp-content/uploads/2014/06/Ecetoc_Tra_Standalone_Consumer_Tool_User_Guide_Jun2014.pdf.*

7. Toxicology Excellence for Risk Assessment (TERA). Complex Exposure Tool (ComET) Meeting Materials. 2009. *http://www.tera.org/Peer/Exposure/ExposureMeetingMaterials.htm.*

8. USEPA. Framework for Human Health Risk Assessment to Inform Decision Making. EPA/100/R-14/001 Office of the Science Advisor, Risk Assessment Forum. 2014. *https://archive.epa.gov/raf/web/pdf/hhra-framework-final-2014.pdf*.

9. National Research Council. Science and Decisions: Advancing Risk Assessment. The National Academies Press. Washington, D.C. 2009.

10. USEPA. Weight of Evidence in ecological risk assessment. Office of Research and Development. Washington, D.C. 2016.

11. Institute of Medicine. Finding What works in Health Care: Standards for Systematic Reviews. p. 13-34. The National Academies Press. Washington, D.C. 2011.

12. J. Higgins and S. Green. Cochrane Handbook for Systematic Reviews of Interventions. John Wiley & Sons. 2011.

13. National Research Council. Review of EPA's Integrated Risk Information System (IRIS) Process. Board on Environmental Studies and Toxicology. Washington, D.C. 2014.

14. Stephens, M.F., Betts, K., Beck, N.B., Cogliano, V., Dickersin, K., Fitzpatrick S.,

Freeman, J., Gray, G., Hartung T., McPartland, J., Rooney A.A., Scherer R.W., Verloo, D., Hoffmann, S.. The Emergence of Systematic Review in Toxicology. Toxicological Sciences. 152 (1): 10-16. 2016. DOI: *https://doi.org/10.1093/toxsci/kfw059*.

15. USEPA. Risk Assessment Guidelines. *https://www.epa.gov/risk/risk-assessment-guidelines.*

16. USEPA. Pesticide Science and Assessing Pesticide Risks. *https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks.*

17. USEPA. Predictive Models and Tools for Assessing Chemicals under the Toxic Substances Control Act (TSCA). *https://www.epa.gov/tsca-screening-tools.*

18. Office of Management and Budget Final Information Quality Bulletin for Peer Review. Washington, D.C. 2004. *https://19january2017snapshot.epa.gov/sites/production/files/2015-01/documents/omb_final_info_quality_bulletin_peer_review_2004_1.pdf.*

19. USEPA. Peer Review Handbook. 3rd ed. EPA/100/B-06/002. Science Policy Council. Washington, D.C. 2006. *https://www.epa.gov/osa/peer-review-handbook-4th-edition-2015*.

VII. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/laws-regulatios/laws-and-executive-orders*.

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

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735,

October 4, 1993) and 13563 (76 FR 3821, January 21, 2011), and any changes made in response to OMB recommendations are documented in the docket. EPA conducted an analysis of the potential costs associated with this action. This analysis, can be found in Unit V. This action is not subject to the requirements of Executive Order 13771, entitled "Reducing Regulation and Controlling Regulatory Costs" (82 FR 9339, February 3, 2017) because this rule results in no more than *de mimimis* costs.

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq*. Specifically, EPA has prepared an ICR to estimate the potential burden and costs associated with the requirements for submitting a request for an Agency-conducted risk evaluation on a particular chemical substance. The ICR, which is available in the docket, has been assigned the EPA ICR number 2559.01. You can find a copy of the ICR in the docket for this rule (Ref. [Insert reference #]), and it is briefly summarized here.

Respondents/affected entities: Manufacturers (including importers).

Respondent's obligation to respond: Optional, i.e., needed only if they are requesting an EPA-conducted risk evaluation for a particular chemical substance.

Estimated number of respondents: 5.

Frequency of response: On occasion.

Total estimated annual burden: 419.2 hours. Burden is defined in 5 CFR 1320.3(b).

Total estimated annual cost: $282,861 for burden hours. There are no O&M 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.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities. Although this rule primarily addresses internal EPA procedures and activities associated with conducting risk evaluations for chemical substances as required by TSCA, EPA is also including the process and content requirements for a manufacturer (including importer) to request that EPA conduct a risk evaluation on particular uses of interest of a chemical substance. EPA has determined that the process and content requirements proposed will have minimal impact on an entity, regardless of size, because there is no mandate for them to make such a request, and the information they must provide should they decide to make such a request, which involves basic information about the chemical substance and the manufacturer's reasons for requesting the EPA-conducted risk evaluation on that chemical substance, should be readily available to the manufacturer. Estimated potential burden and costs are presented in the ICR (Ref. 1).

EPA developed estimates for the number of manufacturers likely to submit a request for a chemical substance to be considered for a risk evaluation. EPA has never collected submissions of this nature in the past, so the actual number of expected submissions is unknown. EPA estimates five manufacturer-requested submissions may be sent to EPA in any given year. Based on the average number of manufacturers (and small businesses) per chemical for the ten chemicals initially identified by EPA for risk evaluation, EPA estimates an average of 35 manufacturers will be involved with the five manufacturer-requested submissions for risk evaluations each year. Of the 35 affected manufacturers, 15 are

estimated to be small businesses. Based on the ten chemicals initially identified by EPA for risk evaluations, there are an average of seven manufacturers per chemical. Assuming that submission costs are shared equally within a consortium of seven manufacturers, the one-time respondent cost of $56,572 per submission would be $8,082 per manufacturer.

Based on revenue data from U.S. Census Statistics of US Business and an estimated cost of $8,082 per manufacturer, EPA estimated the proportion of small manufacturer firms that could have a cost impact of less than 1%; between 1% and 3%; and more than 3% of the average revenues. The proportion of small business firms which may incur a cost impact of less than 1% of the average revenues is 76% of the small firms (approximately 11 of the 15 affected small manufacturers). The proportion of small business firms which may incur a cost impact between 1% and 3% of the average revenues is 23% of the small firms (approximately 3 of the 15 affected small manufactures). The proportion of small business firms which may incur a cost impact greater than 3% of the average revenues is 1% of the small firms (approximately 1 of the 15 small manufacturers).

The decision to request a risk assessment for a chemical is voluntary and manufacturers may decide not to make such a request. But if such a request is made, the burden for the needed paperwork still does not result in a significant economic impact on a substantial number of small entities.

D. Unfunded Mandates Reform Act (UMRA)

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

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). 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.

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

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

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

The EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-201 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

H. 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.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve any technical standards, and is therefore not subject to considerations under NTTAA section 12(d), 15 U.S.C. 272 note.

J. Executive Order 12898: Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations

This action does not establish an environmental health or safety standard, and is therefore not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This is a procedural rule that will not affect the level of protection provided to human health or the environment.

K. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 et seq., and EPA will submit a rule report to the U.S. Senate, and the U.S. House of Representatives, and the Comptroller General of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 702

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

Dated: June 22, 2017.

E. Scott Pruitt,
Administrator.

Therefore, it is proposed that 40 CFR chapter I, subchapter R, be amended as follows:

PART 702 -- [AMENDED]

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

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

2. Add subpart B to read as follows:

PART 702 – GENERAL PRACTICES AND PROCEDURES

* * * * *

Subpart B – Procedures for Chemical Substance Risk Evaluations

702.31 General Provisions.

702.33 Definitions.

702.35 Chemical Substances Designated for Risk Evaluation.

702.37 Submission of Manufacturer Requests for Risk Evaluations.

702.39 Interagency Collaboration.

702.41 Evaluation Requirements.

702.43 Risk Characterization.

702.45 Peer Review.

702.47 Unreasonable Risk Determination.

702.49 Risk Evaluation Timeframes and Actions.

702.51 Publically Available Information.

* * * * *

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

§702.31 General Provisions.

(a) *Purpose*. This subpart establishes the EPA process for conducting a risk

evaluation to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment as required under TSCA section 6(b)(4)(B) (15 U.S.C. 2605(b)(4)(B)).

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

(c) *Applicability.* The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)).

(d) *Enforcement*. Submission to EPA of inaccurate, incomplete, or misleading information pursuant to a risk evaluation conducted pursuant to 15 U.S.C. 2605(b)(4)(B) is a prohibited act under 15 U.S.C. 2614, subject to penalties under 15 U.S.C. 2615 and Title 18 of the U.S. Code.

§702.33 Definitions.

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

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

Aggregate exposure means the combined exposures to an individual from a single chemical substance across multiple routes and across multiple pathways.

EPA means the U.S. Environmental Protection Agency.

Best available science means science that is reliable and unbiased. Use of best available science involves the use of supporting studies conducted in accordance with sound and objective science practices, including, when available, peer reviewed science and supporting studies and data collected by accepted methods or best available methods (if the

reliability of the method and the nature of the decision justifies use of the data). Additionally, EPA will consider as applicable:

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

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

Pathways means the mode through which one is exposed to a chemical substance, including but not limited to: food, water, soil, and air.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Agency 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.

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

Routes means the particular manner by which a chemical substance may contact the body, including absorption via ingestion, inhalation, or dermally (integument).

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

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

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

Weight of scientific evidence means a systematic review method, applied in a manner suited to the nature of the evidence or decision, that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

§702.35 Chemical Substances Designated for Risk Evaluation.

(a) *Chemical Substances Undergoing Risk Evaluation.* A risk evaluation for a chemical substance designated by the Agency as a High-Priority Substance pursuant to the prioritization process described in subpart A, identified under 15 U.S.C. 2605(b)(2)(A), or initiated at the request of a manufacturer or manufacturers under 40 CFR 702.37, will be conducted in accordance with this part, except that risk evaluations that are initiated prior to the effective date of this rule will be conducted in accordance with this part to the maximum extent practicable.

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

(c) *Manufacturer Requests for Work Plan Chemical Substances.* Manufacturer requests for risk evaluations, described in 40 CFR 702.35(a), for chemical substances that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments will be granted at the discretion of the Agency. Such evaluations are not subject to the percentage requirements in 40 CFR 702.35(b).

§702.37 Submission of Manufacturer Requests for Risk Evaluations.

(a) *General Provision.* Any request that EPA conduct a risk evaluation pursuant to this part must comply with all the procedures and criteria in this section to be eligible to be granted by EPA.

(b) *Method for Submission.* One or more manufacturers of a chemical substance may request that EPA conduct a risk evaluation. All requests submitted to EPA under this subpart

must be submitted via the EPA Central Data Exchange (CDX) found at http://cdx.epa.gov. 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 A request for risk evaluations of a category of chemical substances must include an explanation of why the category is appropriate under 15 U.S.C. 2625(c), and EPA will grant such request only upon determining that the requested category is appropriate for risk evaluation.

(3) The manufacturer must identify the circumstances on which they are requesting that EPA conduct a risk evaluation and include a rationale for why these circumstances constitute conditions of use under 702.33.

(4) The request must also include a list of all the existing information that is relevant to whether the chemical substance, under the circumstances identified by the manufacturer(s), presents an unreasonable risk of injury to health or the environment. The list must be accompanied by an explanation as to why such information is adequate to permit EPA to complete a risk evaluation addressing the circumstances identified by the manufacturer(s), The request need not include copies of the information; citations are sufficient, if the information is publically available. The request must include or reference all available information on the health and environmental hazard(s) of the chemical substance, human and environmental exposure(s), and exposed population(s), as relevant to the

circumstances identified in the request. At a minimum, this must include all the following, as relevant to the circumstances identified:

(A) The chemical substance's hazard and exposure potential;

(B) The chemical substance's persistence and bioaccumulation;

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

(D) 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);

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

(F) Any other information relevant to the potential risks of the chemical substance under the circumstances identified in the request.

(4) The request must include a commitment to provide to EPA any referenced information upon request.

(5) Scientific information submitted must be consistent with the scientific standards in 15 U.S.C. 2615(h).

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

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

1. The company named in this request manufacturers the chemical substance identified for risk evaluation.

2. All information provided in the notice is complete and accurate as of the date of

the request.

3. I have either identified or am submitting all information in my possession, control, and a description of all other data known to or reasonably ascertainable by me as required for this request 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.

(c) *Optional Elements*. A manufacturer may provide 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.*

(1) Persons submitting a request under this subpart are subject to EPA confidentiality regulations at 40 CFR part 2, subpart B.

(2) In submitting a claim of confidentiality, a person must certify the accuracy of the following statements concerning all information claimed as confidential:

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate. I further certify that, pursuant to 15 U.S.C. 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

(i) My company has taken reasonable measures to protect the confidentiality of the information;

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and

(iv) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(3) Each claim of confidentiality, other than a claim pertaining to information described in TSCA section 14(c)(2), must be accompanied by a substantiation in accordance with 15 U.S.C. 2613.

(4) Manufacturers must supply a structurally descriptive generic name where specific chemical identity is claimed as CBI.

(5) Any knowing and willful misrepresentation, under this section, is subject to criminal penalty pursuant to 18 U.S.C. 1001.

(e) *EPA Process for Evaluating Manufacturer Requests.*

(1) *Review for completeness.* Upon receipt of the request, EPA will verify that the request is facially complete, i.e., that information has been submitted that appears to be consistent with the requirements in 40 CFR 702.37(b) through (d). EPA will inform the submitting manufacturer(s) if EPA has determined that the request is incomplete, and cannot be processed. Facially complete requests will be processed as described in this subpart.

(2) *Public notification of receipt of request.* Within 15 business days of receipt of a facially complete submission, EPA will notify the public of receipt of the manufacturer request. This notification will include any information submitted by the manufacturer that is not CBI, including the condition(s) of use for which the evaluation is requested.

(3) *Conditions of use to be evaluated.* EPA will assess whether the circumstances identified in the request constitute condition of use under section 702.33, and whether those conditions of use warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will also assess what, if any, additional conditions of use that warrant inclusion within the scope of a risk evaluation for the chemical substance. EPA will conduct these assessments and make proposed determinations based on the same considerations applied in the same manner as it would for a risk evaluation for a high-priority substance.

(4) *Public notice and comment.* No later than 60 business days of receiving a request that EPA has determined to be complete under paragraph (e)(1), 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 45 calendar day public comment period. The docket will contain the manufacturer request (excluding information claimed as CBI) and EPA' proposed additions of conditions of use as described in paragraph (3), and the basis for these proposed additions. During the comment period the public may submit comments and information relevant to the requested risk evaluation, in particular, commenters are encouraged to identify any information not included in the request or the proposed determinations that the commenters believe would be needed to conduct a risk evaluation, and to provide any other information relevant to EPA's proposed determinations of the conditions of use, such as information on other conditions of use of the chemical than those included in the request or in EPA's proposed determinations

(5) *Supplementation of original request.*

(A) At any time prior to the end of the comment period, the requesting manufacturer(s) may supplement the original request with any new information it receives.

(B) At any point prior to the completion of a risk evaluation pursuant to this section, manufacturer(s) must supplement the original request with any information that meets the criteria in 15 U.S.C. 2607(e) and 40 CFR 702.37, or with any other information that has the potential to change EPA's risk evaluation with respect to the conditions of use as requested by the manufacturer. Such information must be submitted consistent with section 8(e) if the information is subject to that section or otherwise within 30 calendar days of the manufacturer's obtaining the information.

(6) *EPA's decision.*

(A) Within 60 days of the end of the comment period provided in paragraph (e)(4), 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.

(B) EPA will grant the request if it determines that all of the following have been met:

(i) that the circumstances identified in the request constitute conditions of use that warrant inclusion in a risk evaluation for the chemical substance;

(ii) that EPA has all of the information needed to conduct such risk evaluation on the conditions of use that were the subject of the request; and

(iii) all other criteria and requirements of this section have been met.

(C) At the end of this 60-day period, EPA will notify the submitting manufacturer(s) of its decision and include the basis for granting or denying the request. Bases for a denial, include the manufacturer has not provided sufficient information to complete the risk evaluation on the condition(s) of use requested, or that the circumstances identified in the request either do not constitute conditions of use, or the conditions of use do not warrant

inclusion in a risk evaluation for the chemical substance. This notification will also identify any additional conditions of use, as determined by the Administrator, that will be included in this risk evaluation.

(D) Within 30 days of receipt of EPA's notification the requester(s) may withdraw the request.

(7) *Public notice of decision.* EPA will make public EPA's decision to grant or deny the request at the time that EPA notifies the manufacturer.

(8) *Compliant request.* EPA will initiate a risk evaluation for all requests for non-TSCA Work Plan Chemicals that meet the criteria in this subpart, until EPA determines that the number of manufacturer-requested chemical substances undergoing risk evaluation is equal to 25% of the High-Priority Substances identified in subpart A as undergoing risk evaluation. Once that level has been reached, EPA will initiate at least one new manufacturer-requested risk evaluation for each manufacturer-requested risk evaluation completed so long as there are sufficient requests that meet the criteria of this subpart, as needed to ensure that the number of manufacturer-requested risk evaluations is equal to at least 25% of the High-Priority substances risk evaluation and not more than 50%.

(9) *Preferences.* In conformance with 40 CFR 702.35(c), in evaluating requests for TSCA Work Plan Chemicals and requests for non-TSCA Work Plan chemicals in excess of the 25% threshold in paragraph (4)(B), EPA will first give preference to requests for risk evaluations on chemical substances:

(A) First, for which the Agency 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

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

(10) *No preferential treatment.* Once granted, EPA will initiate the risk evaluation and thereafter will conduct the risk evaluation following the procedures in §§ 702.39-702.51. EPA will not expedite or otherwise provide special treatment to a risk evaluation conducted as a result of a manufacturer's request.

(11) *Fees.* Manufacturers must pay fees to support risk evaluations as specified under 15 U.S.C. 2605(b)(4)(E)(ii).

§702.39 Interagency collaboration.

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

§702.41 Evaluation Requirements.

(a) *Considerations.*

(1) Each risk evaluation will include all of the following components:

(A) a Scope, including a Conceptual Model and an Analysis Plan;

(B) a Hazard Assessment;

(C) an Exposure Assessment;

(D) a Risk Characterization; and

(E) a Risk Determination.

(2) EPA guidance will be used, as applicable where it represents the best available science appropriate for the particular risk evaluation.

(3) Where appropriate, a risk evaluation will be conducted on a category of chemical substances. EPA will determine whether to conduct an evaluation on a category of chemical substances, and the composition of the category based on the considerations listed in 15

U.S.C. 2625(c).

(4) EPA will document that it has used the best available science and weight of scientific evidence approaches in the risk evaluation process.

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

(6) 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.

(7) To the extent a determination as to the level of risk presented by a condition of use can be made, for example, using assumptions, uncertainty factors, and models or screening methodologies, EPA may determine that no further information or analysis is needed to complete its risk evaluation of the condition(s) of use.

(8) In general, EPA intends to determine whether a chemical substance does or does not present an unreasonable risk under all of the conditions of use within the scope of the risk evaluations, and intends to identify the individual conditions of use or categories of conditions of use that are responsible for such determinations.

(9) Within the time frame in 40 CFR 702.43(d), EPA will complete the risk evaluation of the chemical substance addressing all of the conditions of use within the scope of the evaluation. However, EPA may complete its evaluation of the chemical substance

under specific conditions of use or categories of conditions of use at any point following the issuance of the final scope document, and issue its determination as to whether the chemical substance under those conditions of use does or does not present an unreasonable risk to health or the environment under those conditions of use. EPA will follow all of the requirements and procedures in this Subpart when it conducts its evaluation of the chemical substance under any individual or specific conditions of use.

(10) In evaluating chemical substances that are metals or metal compounds, EPA will use the *Framework for Metals Assessment of the Office of the Science Advisor, Risk Assessment Forum* dated March 2007, or a successor document that addresses metal risk assessment and is peer reviewed by the Science Advisory Board.

(b) *Information and information sources.*

(1) EPA will base each risk evaluation on reasonably available information.

(2) EPA generally expects to initiate a risk evaluation for a chemical substance when EPA believes that all or most of the information necessary to perform the risk evaluation is reasonably available. EPA expects to use its authorities under the Act, and other information gathering authorities, when necessary to obtain the information needed to perform a risk evaluation for a chemical substance before initiating the risk evaluation for such substance. EPA will use such authorities on a case-by-case basis during the performance of a risk evaluation to obtain information as needed to ensure that EPA has adequate, reasonably available information to perform the evaluation.

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

(4) In conducting risk evaluations, EPA will utilize reasonably available information including information, models, and screening methodologies, as appropriate. The approaches used will be determined by the quality of the information, the deadlines specified in TSCA section 6(b)(4)(G) for completing the risk evaluation, and the extent to which the information reduces uncertainty.

(5) Where appropriate, to the extent practicable, and scientifically justified, EPA will require the development of information generated without the use of new testing on vertebrates in performing risk evaluation.

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

(1) The condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.

(2) The potentially exposed populations, including any potentially exposed or susceptible subpopulations as identified as relevant to the risk evaluation by the Agency under the conditions of use, that EPA plans to evaluate; the ecological receptors that EPA plans to evaluate; and the hazards to health and the environment that EPA plans to evaluate.

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

(4) *A conceptual model.*

(A) The scope documents will include a Conceptual Model that describes actual or predicted relationships between the chemical substance, the conditions of use within the scope of the evaluation and human and environmental receptors.

(B) The Conceptual Model will identify human and ecological health hazards the

EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(C) Conceptual Model development will consider the life cycle of the chemical substance, including manufacture, processing, distribution in commerce, storage, use, and disposal, relevant to the conditions of use within the scope of the evaluation

(5) *An analysis plan.*

(A) The scope documents will include an analysis plan that identifies the approaches, methods, and/or metrics that EPA plans to use to assess exposures, effects, and risk, including associated uncertainty and variability for each risk evaluation. The analysis plan will also identify the strategy for using information, accepted science policies, models, and screening methodologies.

(B) Hypotheses about the relationships identified in the conceptual model will be described. The relative strengths of alternative hypotheses if any will be evaluated to determine the appropriate risk assessment approaches.

(6) The Agency's plan for peer review.

(7) *Developing the scope.*

(A) *Draft scope.* For each risk evaluation to be conducted EPA will publish a document in the **Federal Register** that specifies the draft scope of the risk evaluation the Agency plans to conduct. The document will address the elements in paragraphs (c)(1) through (6).

(B) *Timeframes.* EPA generally expects to publish the draft scope no later than 3 months from the initiation of the risk evaluation process for the chemical substance.

(C) *Public comments.* EPA will allow a public comment period of no less than 45 calendar days during which interested persons may submit comment on EPA's draft risk

evaluation scope. EPA will open a docket to facilitate receipt of public comments.

(D) *Final scope.*

(i) The Agency will, no later than 6 months after the initiation of a risk evaluation, publish a document in the **Federal Register** that specifies the final scope of the risk evaluation the Agency plans to conduct. The document shall address the elements in paragraphs (c)(1) through (6).

(ii) For a chemical substance designated as a High-Priority Substance under 40 CFR 702 subpart A, EPA will not publish the final scope of the risk evaluation until at least 12 months have elapsed from the initiation of the prioritization process for the chemical substance.

(d) *Hazard assessment.*

(1) The hazard information relevant to the chemical substance will be evaluated using hazards identified in the final scope document published pursuant to paragraph (c)(7)(D), for the identified exposure scenarios, including any identified potentially exposed or susceptible subpopulation(s).

(2) The hazard assessment process will identify the types of hazards to health or the environment posed by the chemical substance under the condition(s) of use within the scope of the risk evaluation. Hazard information related to potential health and environmental hazards of the chemical substance will be reviewed in a manner consistent with best available science and weight of scientific evidence as defined in section 702.33 and all assessment methods will be documented. This process includes the identification, evaluation, and synthesis of information to describe the potential health and environmental hazards of the chemical substance.

(3) Relevant potential human and environmental hazards will be evaluated.

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

(5) Studies evaluated may include, but would not be limited to: human epidemiological studies, in vivo and/or in vitro laboratory studies, biomonitoring studies, mechanistic and/or kinetic studies in a variety of test systems, including but not limited to toxicokinetics and toxicodynamics, computational toxicology such as high-throughput assays, genomic response assays, data from structure-activity relationships, and ecological field data.

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

(7) *Human health hazard assessment*. The human health hazard assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(6)(D).

(8) *Environmental health hazard assessment*. The environmental health hazard assessment will consider the relationship between the chemical substance and the occurrence of an ecological hazard elicited.

(e) *Exposure assessment.*

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

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

(3) Exposure information related to potential human health or ecological hazards of

the chemical substance will be reviewed in a manner consistent with the description of best available science and weight of scientific evidence in section 702.33 and all methods will be documented.

(4) *Human health exposure assessment*. The exposure assessment will consider all potentially exposed and susceptible subpopulation(s) determined to be relevant, as identified in the final scope document published pursuant to paragraph (c)(7)(D).

(5) *Environmental health exposure assessment*.

(A) The environmental health exposure assessment will characterize and evaluate the interaction of the chemical substance with the ecological receptors identified in the final scope document published pursuant to paragraph (c)(6)(D).

(B) Exposures considered will include populations and communities, depending on the chemical substance and the ecological characteristic involved.

§702.43 Risk Characterization.

(a) *Risk Characterization Considerations*. EPA will:

(1) integrate the hazard and exposure assessments into quantitative and/or qualitative estimates of risk for the identified populations (including any potentially exposed or susceptible subpopulation(s)) identified in the final scope document published pursuant to paragraph (c)(6)(D) and ecological characteristics for the conditions of use within the scope of the risk evaluation;

(2) describe whether aggregate or sentinel exposures under the conditions of use were considered and the basis for their consideration;

(3) Not consider costs or other nonrisk factors;

(4) Take into account, where relevant, the likely duration, intensity, frequency, and

number of exposures under the condition(s) of use of the chemical substance; and

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

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

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

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

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

(4) *Considerations for environmental risk evaluations*. For environmental risk

evaluations, it may be necessary to discuss the nature and magnitude of the effects, the spatial and temporal patterns of the effects, implications at the individual, species, population, and community level, and the likelihood of recovery subsequent to exposure to the chemical substance.

§702.45 Peer Review.

The *EPA Peer Review Handbook* (2015), the Office of Management and Budget Final Information Quality Bulletin for Peer Review (OMB Bulletin), and other available, relevant and applicable methods consistent with 15 U.S.C. 2625, will serve as the guidance for peer review activities. Peer review will be conducted on the risk evaluations for the chemical substances identified pursuant to 15 U.S.C. 2605(b)(4)(A).

§702.47 Unreasonable Risk Determination.

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 each condition of uses within the scope of the risk evaluation, either in a single decision document or in multiple decision documents.

§702.49 Risk Evaluation Timeframes and Actions.

(a) *Draft risk evaluation timeframe.* EPA will publish a draft risk evaluation in the **Federal Register**, open a docket to facilitate receipt of public comment, and provide no less than a 60-day comment period, during which time the public may submit comment on EPA's draft risk evaluation.

(b) *Final risk evaluation.*

(1) EPA will complete a risk evaluation for the chemical substance under the conditions of use within the scope of the risk evaluation as soon as practicable, but not later

than 3 years after the date on which the Agency initiates the risk evaluation.

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

(3) EPA will publish the final risk evaluation in the **Federal Register**.

(c) *Final determination of unreasonable risk.* Upon determination by the EPA that a chemical substance under one or more of the conditions of use within the scope of the risk evaluation presents an unreasonable risk of injury to health or the environment as described in §702.47, the Agency will initiate action as required pursuant to 15 U.S.C. 2605(a).

(d) *Final determination of no unreasonable risk.* A determination by EPA that the chemical substance, under one or more of the conditions of use within the scope of the risk evaluation, 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.

§702.51 Publically Available Information.

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

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

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

(3) Any information required to be provided to the Agency under 15 U.S.C. 2603;

(4) A nontechnical summary of the risk evaluation;

(5) A list of the studies, with the results of the studies, considered in carrying out each

risk evaluation;

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

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