Title 40 —Protection of Environment
Chapter I —Environmental Protection Agency
Subchapter R —Toxic Substances Control Act

PART 702—GENERAL PRACTICES AND PROCEDURES

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

Source: 47 FR 2773, Jan. 19, 1982, unless otherwise noted.

Subpart A—Procedures for Prioritization of Chemical Substances for Risk Evaluation

Source: 82 FR 33762, July 20, 2017, unless otherwise noted.

§ 702.1 General provisions.

(a) ***Purpose.*** This regulation establishes the risk-based screening process for designating chemical substances as a High-Priority Substance or a Low-Priority Substance for risk evaluation as required under section 6(b) of the Toxic Substances Control Act, as amended (15 U.S.C. 2605(b)).

(b) ***Scope of designations.*** EPA will make priority designations pursuant to these procedures for a chemical substance, not for a specific condition or conditions of uses of a chemical substance.

(c) ***Categories of chemical substances.*** Nothing in this subpart shall be interpreted as a limitation on EPA's authority under 15 U.S.C. 2625(c) to take action, including the actions contemplated in this subpart, on a category of chemical substances.

(d) ***Prioritization timeframe.*** The Agency will publish a final priority designation for a chemical substance in no fewer than 9 months and no longer than 1 year following initiation of prioritization pursuant to § 702.7.

(e) ***Metals or metal compounds.*** EPA will identify priorities for chemical substances that are metals or metal compounds in accordance with 15 U.S.C. 2605(b)(2)(E).

(f) ***Applicability.*** These regulations do not apply to any chemical substance for which a manufacturer requests a risk evaluation under 15 U.S.C. 2605(b)(4)(C).

(g) ***Scientific standards and weight of the scientific evidence.*** EPA's proposed priority designations under § 702.9 and final priority designations under § 702.11 will be consistent with the scientific standards provision in 15 U.S.C. 2625(h) and the weight of the scientific evidence provision in 15 U.S.C. 2625(i).

(h) ***Interagency collaboration.*** EPA will consult with other relevant Federal Agencies during the administration of this subpart.

§ 702.3 Definitions.

For purposes of this subpart, the following definitions apply:

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

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

EPA means the U.S. Environmental Protection Agency.

High-priority substance means a chemical substance that EPA determines, without consideration of costs or other non-risk factors, may present an unreasonable risk of injury to health or the environment because of a potential hazard and a potential route of exposure under the conditions of use, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

Low-priority substance means a chemical substance that EPA concludes, based on information sufficient to establish, without consideration of costs or other non-risk factors, does not meet the standard for a High-Priority Substance.

Potentially exposed or susceptible subpopulation means a group of individuals within the general population identified by the Administrator 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, considering the deadlines specified in 15 U.S.C. 2605(b) for prioritization and risk evaluation. Information that meets such terms is reasonably available information whether or not the information is confidential business information that is protected from public disclosure under 15 U.S.C. 2613.

§ 702.4 [Reserved]

§ 702.5 Candidate selection.

(a) ***General objective.*** In selecting candidates for a High-Priority Substance designation, it is EPA's general objective to select those chemical substances with the greatest hazard and exposure potential first, considering reasonably available information on the relative hazard and exposure of potential candidates. In selecting candidates for Low-Priority Substance designation, it is EPA's general objective to select those chemical substances with hazard and/or exposure characteristics under the conditions of use such that a risk evaluation is not warranted at the time to determine whether the chemical substance presents an unreasonable risk of injury to health or the environment, including an unreasonable risk to potentially exposed or susceptible subpopulations identified as relevant by EPA.

(b) ***Available information.*** EPA expects to ensure that there is reasonably available information to meet the deadlines for prioritization under the Act.

(c) ***Preferences and TSCA work plan.*** In selecting a candidate for prioritization as a High-Priority Substance, EPA will:

(1) Give preference to:

(i) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments as having a persistence and bioaccumulation score of 3; and

(ii) Chemical substances that are listed in the 2014 update of the TSCA Work Plan for Chemical Assessments that are known human carcinogens and have high acute and chronic toxicity; and

(2) Identify a sufficient number of candidates from the 2014 update of the TSCA Work Plan for Chemical Assessments to ensure that, at any given time, at least 50 percent of risk evaluations being conducted by EPA are drawn from that list until all substances on the list have been designated as either a High-Priority Substance or Low-Priority Substance pursuant to § 702.11.

(d) ***Purpose.*** The purpose of the preferences and criteria in paragraphs (a) through (c) of this section is to inform EPA's decision whether or not to initiate the prioritization process pursuant to § 702.7, and the proposed designation of the chemical substance as either a High-Priority Substance or a Low-Priority Substance pursuant to § 702.9.

(e) ***Insufficient information.*** If EPA believes it would not have sufficient information for purposes of prioritization, EPA generally expects to obtain the information necessary to inform prioritization prior to initiating the process pursuant to § 702.9, using voluntary means of information gathering and, as necessary, exercising its authorities under the Act in accordance with the requirements of 15 U.S.C. 2603, 15 U.S.C. 2607, and 15 U.S.C. 2610. In exercising its authority under 15 U.S.C. 2603(a)(2), EPA will identify the need for the information in accordance with 15 U.S.C. 2603(a)(3).

§ 702.7 Initiation of prioritization process.

(a) EPA generally expects to initiate the prioritization process for a chemical substance only when it believes that the information necessary to prioritize the substance is reasonably available.

(b) EPA will initiate prioritization by publishing a notice in the FEDERAL REGISTER identifying a chemical substance for prioritization. EPA will include a general explanation in this notice for why it chose to initiate the process on the chemical substance.

(c) The prioritization timeframe in § 702.1(d) begins upon EPA's publication of the notice described in paragraph (b) of this section.

(d) Publication of the notice in the FEDERAL REGISTER pursuant to paragraph (b) of this section will initiate a period of 90 days during which interested persons may submit relevant information on that chemical substance. Relevant information might include, but is not limited to, any information that may inform the screening review conducted pursuant to § 702.9(a). EPA will open a separate docket for each chemical substance to facilitate receipt of information.

(e) EPA may, in its discretion, extend the public comment period in paragraph (d) of this section for up to three months in order to receive or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B). The length of the extension will be based upon EPA's assessment of the time necessary for EPA to receive and/or evaluate information submitted under 15 U.S.C. 2603(a)(2)(B).

§ 702.9 Screening review and proposed priority designation.

(a) ***Screening review.*** Following the close of the comment period described in § 702.7(d), including any extension pursuant to paragraph (e) of that section, EPA will generally use reasonably available information to screen the candidate chemical substance against the following criteria and considerations:

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

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

(3) Potentially exposed or susceptible subpopulations;

(4) Storage of the chemical substance near significant sources of drinking water;

(5) The chemical substance's conditions of use or significant changes in conditions of use;

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

(7) Other risk-based criteria that EPA determines to be relevant to the designation of the chemical substance's priority.

(b) ***Information sources.*** In conducting the screening review in paragraph (a) of this section, EPA expects to consider sources of information relevant to the listed criteria and consistent with the scientific standards provision in 15 U.S.C. 2625(h), including, as appropriate, sources for hazard and exposure data listed in Appendices A and B of the TSCA Work Plan Chemicals: Methods Document (February 2012).

(c) ***Proposed designation.*** Based on the results of the screening review in paragraph (a) of this section, relevant information received from the public as described in § 702.7(d), and other information as appropriate and consistent with 15 U.S.C. 2625(h) and (i), EPA will propose to designate the chemical substance as either a High-Priority Substance or Low-Priority Substance, along with an identification of the information, analysis, and basis used to support the proposed designation.

(d) ***Costs and non-risk factors.*** EPA will not consider costs or other non-risk factors in making a proposed priority designation.

(e) ***Insufficient information.*** If information remains insufficient to enable the proposed designation of the chemical substance as a Low-Priority Substance after any extension of the initial public comment period pursuant to § 702.7(e), EPA will propose to designate the chemical substance as a High-Priority Substance.

(f) ***Conditions of use.*** EPA will propose to designate a chemical substance as a High-Priority Substance based on the proposed conclusion that the chemical substance satisfies the definition of High-Priority Substance in § 702.3 under one or more activities that the Agency determines constitute conditions of use. EPA will propose to designate a chemical substance as a Low-Priority Substance based on the proposed conclusion that the chemical substance meets the definition of Low-Priority Substance in § 702.3 under the activities that the Agency determines constitute conditions of use.

(g) ***Publication.*** EPA will publish the proposed designation in the FEDERAL REGISTER, along with an identification of the information, analysis and basis used to support a proposed designation, in a form and manner that EPA deems appropriate, and provide a comment period of 90 days, during which time the public may submit comment on EPA's proposed designation. EPA will open a docket to facilitate receipt of public comment.

§ 702.11 Final priority designation.

(a) After considering any additional information collected from the proposed designation process in § 702.9, as appropriate, EPA will finalize its designation of a chemical substance as either a High-Priority Substance or a Low-Priority Substance consistent with 15 U.S.C. 2625(h) and (i).

(b) EPA will not consider costs or other non-risk factors in making a final priority designation.

(c) EPA will publish each final priority designation in the FEDERAL REGISTER, along with an identification of the information, analysis, and basis used to support a final designation consistent with 15 U.S.C. 2625(h), (i) and (j). For High-Priority Substance designations, EPA generally expects to indicate which condition(s) of use were the primary basis for such designations.

(d) As required in 15 U.S.C. 2605(b)(3)(C), EPA will finalize a designation for at least one High-Priority Substance for each risk evaluation it completes, other than a risk evaluation that was requested by a manufacturer pursuant to subpart B of this part. The obligation in 15 U.S.C. 2605(b)(3)(C) will be satisfied by the designation of at least one High-Priority Substance where such designation specifies the risk evaluation that the designation corresponds to, and where the designation occurs within a reasonable time before or after the completion of the risk evaluation.

§ 702.13 Revision of designation.

EPA may revise a final designation of a chemical substance from Low-Priority to High-Priority Substance at any time based on reasonably available information. To revise such a designation, EPA will re-initiate the prioritization process on that chemical substance in accordance with § 702.7, re-screen the chemical substance and propose a priority designation pursuant to § 702.9, and finalize the priority designation pursuant to § 702.11.

§ 702.15 Effect of designation as a low-priority substance.

Designation of a chemical substance as a Low-Priority Substance under § 702.11 means that a risk evaluation of the chemical substance is not warranted at the time, but does not preclude EPA from later revising the designation pursuant to § 702.13, if warranted. Designation as a Low-Priority Substance is not a finding that the chemical substance does not present an unreasonable risk, but rather that it does not meet the High-Priority Substance definition.

§ 702.17 Effect of designation as a high-priority substance.

Final designation of a chemical substance as a High-Priority Substance under § 702.11 initiates a risk evaluation pursuant to subpart B of this part. Designation as a High-Priority Substance is not a final agency action and is not subject to judicial review until the date of promulgation of the associated final rule under section 6(a). Designation as a High-Priority Substance is not a finding that the chemical substance presents an unreasonable risk.

Subpart B—Procedures for Chemical Substance Risk Evaluations

Source: 82 FR 33747, July 20, 2017 as amended at 89 FR 37052, May 3, 2024, unless otherwise noted.

§ 702.31 General provisions.

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

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

(c) ***Applicability.*** The requirements of this part apply to all chemical substance risk evaluations initiated pursuant to TSCA section 6(b) (15 U.S.C. 2605(b)) beginning June 3, 2024. For risk evaluations initiated prior to this date, but not yet finalized, EPA will seek to apply the requirements in this subpart to the extent practicable. These requirements shall not apply retroactively to risk evaluations already finalized.

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

§ 702.33 Definitions.

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

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

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

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

EPA means the U.S. Environmental Protection Agency.

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

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

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

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

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

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

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

§ 702.35 Chemical substances subject to risk evaluation.

(a) ***Chemical substances undergoing risk evaluation.*** A risk evaluation for a chemical substance designated by EPA as a High-Priority Substance pursuant to the prioritization process described in subpart A or initiated at the request of a manufacturer or manufacturers under § 702.45, will be conducted in accordance with this part, subject to § 702.31(c).

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

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

§ 702.37 Evaluation requirements.

(a) ***Considerations.***

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

(2) EPA will document that the risk evaluation is consistent with the best available science and based on the weight of the scientific evidence. In determining best available science, EPA shall consider as applicable:

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

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

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

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

(v) The extent of independent verification or peer review of the information or of the procedures, measures, methods, protocols, methodologies or models.

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

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

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

(b) ***Information and information sources.***

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

(2) EPA will apply systematic review methods to assess reasonably available information, as needed to carry out risk evaluations that meet the requirements in TSCA section 26(h) and (i), in a manner that is objective, unbiased, and transparent.

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

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

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

§ 702.39 Components of risk evaluation.

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

(1) A Scope;

(2) A Hazard Assessment;

(3) An Exposure Assessment;

(4) A Risk Characterization; and

(5) A Risk Determination.

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

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

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

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

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

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

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

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

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

(c) ***Hazard assessment.***

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

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

(3) Consistent with § 702.37(b), information evaluated may include, but would not be limited to: Human epidemiological studies, in vivo and/or in vitro laboratory studies, biomonitoring and/or human clinical studies, ecological field data, read across, mechanistic and/or kinetic studies in a variety of

test systems. These may include but are not limited to: toxicokinetics and toxicodynamics (*e.g.,* physiological-based pharmacokinetic modeling), and computational toxicology (*e.g.,* high-throughput assays, genomic response assays, data from structure-activity relationships, in silico approaches, and other health effects modeling).

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

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

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

(d) ***Exposure assessment.***

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

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

(3) Consistent with § 702.37(b), information evaluated may include, but would not be limited to: chemical release reports, release or emission scenarios, data and information collected from monitoring or reporting, release estimation approaches and assumptions, biological monitoring data, workplace monitoring data, chemical exposure health data, industry practices with respect to occupational exposure control measures, and exposure modeling.

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

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

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

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

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

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

(e) ***Risk characterization.***

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

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

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

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

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

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

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

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

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

(f) ***Risk determination.***

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

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

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

§ 702.41 Peer review.

EPA will conduct peer review activities on risk evaluations conducted pursuant to 15 U.S.C. 2605(b)(4)(A). EPA expects such activities, including decisions regarding the appropriate scope and type of peer review, to be consistent with the applicable peer review policies, procedures, and methods in guidance promulgated by the Office of Management and Budget and EPA, and in accordance with 15 U.S.C. 2625(h) and (i).

§ 702.43 Risk evaluation actions and timeframes.

(a) ***Draft scope.***

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

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

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

(b) ***Final scope.***

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

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

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

(d) ***Final risk evaluation.***

(1) EPA will complete and publish a final risk evaluation for the chemical substance under the conditions of use as soon as practicable, but not later than 3 years after the date on which EPA initiates the risk evaluation. The document shall include the elements in § 702.39(c) through (f) and EPA will publish a notice of availability in the FEDERAL REGISTER.

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

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

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

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

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

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

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

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

§ 702.45 Submission of manufacturer requests for risk evaluations.

(a) ***General provisions.***

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

(vii) Consumer products containing the chemical;

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

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

(6) Where information described in paragraph (c)(4) or (5) of this section is unavailable, an explanation as to why, and the rationale for why, in the requester's view, the provided information is nonetheless sufficient to allow EPA to complete a risk evaluation on the chemical substance.

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

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

> I certify that to the best of my knowledge and belief:
>
> (A) The company named in this request manufactures the chemical substance identified for risk evaluation.
>
> (B) All information provided in the request is complete and accurate as of the date of the request.
>
> (C) I have either identified or am submitting all information in my possession and control, and a description of all other data known to or reasonably ascertainable by me as required under this part. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information in this request and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment.

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

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

(e) ***EPA process for reviewing requests.***

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

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

(3) ***Public notice and comment.*** No later than 90 days after initially determining a request to be complete pursuant to paragraph (e)(2) of this section, EPA will submit for publication the receipt of the request in the FEDERAL REGISTER, open a docket for that request and provide no less than a 60-day public comment period. The docket will contain the CBI sanitized copies of the request and all supporting information. The notice will encourage the public to submit comments and information relevant to the manufacturer-requested risk evaluation, including, but not limited to, identifying information not provided in the request, information the commenter believes necessary to conduct a risk evaluation, and any other information relevant to the conditions of use.

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

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

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

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

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

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

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

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

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

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

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

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

(i) ***Supplementation of original request.*** At any time prior to the end of the comment period described in paragraph (e)(6) of this section, the requesting manufacturer(s) may supplement the original request with any new information that becomes available to the requesting manufacturer(s). At any point prior to the completion of a manufacturer-requested risk evaluation pursuant to this section, the requesting manufacturer(s) must supplement the original request with any information that meets the criteria in 15 U.S.C. 2607(e) and this section, or with any other reasonably ascertainable information that has the

potential to change EPA's risk evaluation. Such information must be submitted consistent with 15 U.S.C. 2607(e) if the information is subject to that section or otherwise within 30 days of when the requesting manufacturer(s) obtain the information.

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

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

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

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

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

(k) ***Fees.*** Manufacturers must pay fees to support risk evaluations as specified under 15 U.S.C. 2605(b)(4)(E)(ii), and in accordance with 15 U.S.C. 2625(b) and 40 CFR 700.45. In the event that a request for a risk evaluation is withdrawn by the requesting manufacturer pursuant to paragraph (g) of this section, the total fee amount due will be either, in accordance with 40 CFR 700.45(c)(2)(x) or (xi) (as adjusted by 40 CFR 700.45(d) when applicable), 50% or 100% of the actual costs expended in carrying out the risk evaluation as of the date of receipt of the withdrawal notice. The payment amount will be determined by EPA, and invoice or refund issued to the requesting manufacturer as appropriate.

§ 702.47 Interagency collaboration.

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

§ 702.49 Publicly available information.

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

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

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

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

(d) A nontechnical summary of the risk evaluation;

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

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

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

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

Subpart C—Citizen Suit

§ 702.60 Purpose.

Section 20 of the Toxic Substances Control Act (TSCA) authorizes any person to begin a civil action to compel performance by the Environmental Protection Agency (EPA) of TSCA non-discretionary acts or duties (section 20(a)(2)) or to restrain any violation of TSCA, or of any rule promulgated under sections 4, 5, or 6, or of any order issued under section 5 of TSCA (section 20(a)(1)). The purpose of this regulation is to prescribe procedures governing the giving of a notice of intent to file suit required by section 20(b) of TSCA as a prerequisite to beginning such civil actions.

§ 702.61 Service of notice.

(a) ***Notice as a prerequisite to suit.*** Under section 20 of TSCA, no civil action may be commenced by a citizen to restrain a violation of TSCA, or a rule or order thereunder, unless at least 60 days in advance the citizen has given notice of the intent to file suit to the Administrator and to the person who is alleged to have committed the violation. No civil action may be commenced by a citizen to compel the Administrator to perform any non-discretionary act or duty under TSCA, unless at least 60 days in advance the citizen has given notice of the intent to file suit to the Administrator. However, in the case of an alleged failure by the Administrator to file an action under section 7 of TSCA, the citizen must give notice to the Administrator only 10 days in advance of filing the civil action.

(b) ***Method of service.*** Notice of intent to file suit can be either personally served or served by certified mail—return receipt requested—to persons identified in paragraph (d) of this section.

(c) ***Date of service.*** The effective date of service of a notice given in accordance with this rule shall be the date of the return receipt, if served by mail, or the date of receipt if personally served.

(d) ***Persons to be served*** —

(1) ***Violations of TSCA rules or TSCA order.***

(i) If the alleged violator is a private individual or a corporation, notice of intent to file suit shall be served on the individual or the owner or managing agent of the plant, facility, or activity alleged to be in violation. If the alleged violator is a corporation, a copy of the notice shall also be sent to the registered agent, if any, of such corporation in the State in which such violation is alleged to have occurred. Notice shall also be served on the Administrator of the EPA.

(ii) If the alleged violator is a State or local government entity, notice of intent to file suit shall be served on the head of the agency. Notice shall also be served on the Administrator of the EPA, and a copy shall be sent to the Attorney General of the United States.

(iii) If the alleged violator is a Federal agency, notice of intent to file suit shall be served on the head of the agency. Notice shall also be served on the Administrator of the EPA, and a copy shall be sent to the Attorney General of the United States.

(2) ***Performance of non-discretionary TSCA acts or duties.*** Notice of intent to file suit shall be served on the Administrator of the EPA and a copy shall be sent to the Attorney General of the United States.

(3) ***Address of persons to be served.***

(i) EPA Administrator: 1200 Pennsylvania Ave., NW., Washington, DC 20460.

(ii) Attorney General of the United States: 10th and Constitution Avenue, NW., Washington, DC 20530.

§ 702.62 Contents of notice.

(a) ***Violation of TSCA rule or TSCA order.*** Notice of intent to file suit regarding an alleged violation of TSCA or any rule promulgated under sections 4, 5, or 6, or an order issued under section 5, shall include sufficient information to permit the recipient to identify:

(1) The specific provision of TSCA or of the rule or order under TSCA alleged to have been violated.

(2) The activity alleged to constitute a violation.

(3) The person or persons responsible for the alleged violation.

(4) The location of the alleged violation.

(5) The date or dates of the alleged violation as closely as the citizen is able to specify them.

(6) The full name, address, and telephone number of the citizen giving notice.

(b) ***Failure to act.*** Notice regarding an alleged failure of the Administrator to perform any act or duty which is not discretionary shall:

(1) Identify the specific provision of TSCA which requires an act or creates a duty.

(2) Describe with reasonable specificity the action taken or not taken by the Administrator which is alleged to constitute a failure to perform the act or duty.

(3) State the full name, address, and telephone number of the citizen giving the notice.

(c) ***Identification of Counsel.*** The notice shall state the name, address, and telephone number of the Legal Counsel, if any, representing the citizen giving the notice.