EPA has determined to grant the request and the appropriate initial remittance under §700.45(c) has been submitted as provided in §700.45(g).

(d) Failure to submit the appropriate final remittance specified under §700.45(c) for a manufacturer-requested risk evaluation as provided in §700.45(g) is a violation of TSCA and enforceable under section 15 of the Act.

[83 FR 52719, Oct. 17, 2018]

PART 702—GENERAL PRACTICES AND PROCEDURES

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

Sec.

Subpart B—Procedures for Chemical Substance Risk Evaluations

Subpart C—Citizen Suit

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, 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)).

(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.

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:

(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.

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 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 § 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 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 the Agency. Such evaluations are not subject to the percentage requirements in paragraph (b) of this section.

§ 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:

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

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

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

(iv) 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);

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

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

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

(6) Scientific information submitted must be consistent with the scientific standards in 15 U.S.C. 2625(h).

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

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

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

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

(C) 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.

(ii) [Reserved]

(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) 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:

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

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

(C) 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

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

(ii) [Reserved]

(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 paragraphs (b) through (d) of this section. 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 § 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) 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 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 (e)(3) of this section, 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.* (i) 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.

(ii) 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 this section, 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.* (i) Within 60 days of the end of the comment period provided in paragraph (e)(4) of this section, EPA will review the request along with any additional information received during the comment period to determine whether the request meets the criteria and requirements of this section.

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

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

(B) 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

(C) All other criteria and requirements of this section have been met.

(iii) 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.

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

(i) 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

(ii) 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 through 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).

[82 FR 33747, July 20, 2017]

EFFECTIVE DATE NOTE: At 88 FR 37166, June 7, 2023, § 702.37 was amended by revising paragraph (d), effective Aug. 7, 2023. For the convenience of the user, the revised text is set forth as follows:

§ 702.37 Submission of manufacturer requests for risk evaluations.

* * * * *

(d) *Confidential business information.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

* * * * *

§ 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:

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

(ii) A Hazard Assessment;

(iii) An Exposure Assessment;

(iv) A Risk Characterization; and

(v) 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 § 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) 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 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:

(i) 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.

(ii) The conceptual model will identify human and ecological health hazards the EPA plans to evaluate for the exposure scenarios EPA plans to evaluate.

(iii) 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:

(i) 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.

(ii) 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.

(i) *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) of this section.

(ii) *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.

(iii) *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.

(8) 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) of this section.

(ii) 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.

(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)(8) of this section, 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 §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) 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)(8) of this section.

(8) 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 §702.33 and all methods will be documented.

(4) The human health 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)(8) of this section.

(5) Environmental health exposure assessment:

(i) 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)(8) of this section.

(ii) 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 § 702.41(c)(8) 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:

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

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

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 nondiscretionary 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.

PART 703—CONFIDENTIALITY CLAIMS (EFF. 8-7-23)

Sec.

AUTHORITY: 15 U.S.C. 2613.

SOURCE: 88 FR 37166, June 7, 2023, unless otherwise noted.

EFFECTIVE DATE NOTE: At 88 FR 37166, June 7, 2023, part 703 was added, effective Aug. 7, 2023.