

No. 17-72260 (and consolidated Case Nos. 17-72501, 17-72968, 17-73290, 17-73383,  
17-73390)

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**IN THE UNITED STATES COURT OF APPEALS  
FOR THE NINTH CIRCUIT**

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SAFER CHEMICALS HEALTHY FAMILIES, et al.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ET AL.,

Respondents.

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ON PETITION FOR JUDICIAL REVIEW OF ACTIONS BY THE UNITED  
STATES ENVIRONMENTAL PROTECTION AGENCY

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**BRIEF OF RESPONDENTS UNITED STATES ENVIRONMENTAL  
PROTECTION AGENCY, ET AL.**

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## GLOSSARY

ER	Petitioners' Excerpts of Record, Dkt. 45
EPA	Respondent United States Environmental Protection Agency
Prioritization Rule	Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, 82 Fed. Reg. 33,753 (July 20, 2017)
Risk Evaluation Rule	Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726 (July 20, 2017)
SER	Respondent's Supplemental Excerpts of Record
TSCA (or Act)	Toxic Substances Control Act

## JURISDICTION

Three groups of petitioners<sup>1</sup> filed petitions on August 11, 2017, seeking review of two rulemakings issued by Respondent United States Environmental Protection Agency (EPA or Agency).<sup>2</sup> The first, issued under EPA's authority in 15 U.S.C. § 2605(b)(1)(A), is entitled "Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act" and published at 82 Fed. Reg. 33,753 (July 20, 2017) (Prioritization Rule). The second, issued under EPA's authority in 15 U.S.C. § 2605(b)(4)(B), is entitled "Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act" and published at 82 Fed. Reg. 33,726 (July 20, 2017) (Risk Evaluation Rule). To the extent Petitioners challenge the regulatory provisions and binding statutory interpretations, this Court has jurisdiction under 15 U.S.C. § 2618(a). However, certain of Petitioners' claims seek review of

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<sup>1</sup> Safer Chemicals Healthy Families; Alaska Community Action on Toxics; Environmental Health Strategy Center; Environmental Working Group; Learning Disabilities Association of America; Sierra Club; Union of Concerned Scientists; United Steel, Paper and Forestry, Rubber, Manufacturing, Energy, Allied Industrial and Service Workers International Union, AFL-CIO/CLC; We Act for Environmental Justice; Asbestos Disease Awareness Organization; and Vermont Public Interest Research Group petitioned for review in Case Nos. 17-72260 and 17-73390. The Alliance of Nurses for Health Environments, Cape Fear River Watch, and Natural Resources Defense Council petitioned for review in Case Nos. 17-72968 and 17-73290. The Environmental Defense Fund petitioned for review in Case Nos. 17-72501 and 17-73383.

<sup>2</sup> Petitioners originally named Scott Pruitt, the former Administrator of EPA. Pursuant to Federal Rule of Appellate Procedure 42(c)(2); his successor, acting Administrator Andrew Wheeler, has automatically been substituted as a party.

EPA's nonbinding preamble discussions. This Court does not have jurisdiction to entertain challenges to statements about actions EPA may or may not take in the future. *See infra* Argument Part II.B.

### ISSUES PRESENTED

A critical goal of TSCA section 6 is for EPA to quickly identify, evaluate, and regulate chemicals that present unreasonable risks under their “conditions of use.”

1. TSCA unambiguously grants EPA discretion to determine what constitutes a chemical's conditions of use, “as determined by the Administrator.” 15 U.S.C. § 2602(4). Given the limited tools under TSCA for regulating historical activities and legislative history indicating that Congress intended for EPA to focus on prospective and ongoing activities, did EPA reasonably interpret the phrase “conditions of use” to exclude legacy activities?
2. Mirroring the statutory language, the Risk Evaluation Rule states that EPA will publish a scope document outlining “the condition(s) of use . . . that the EPA plans to consider in the risk evaluation.” 40 C.F.R. § 702.41(c)(1).
  - a. Conditional, equivocal, and nonbinding statements in a regulatory preamble are not final agency action and do not give rise to non-speculative injury. Does this Court lack jurisdiction to review preamble statements in the Risk Evaluation Rule that EPA “may,” on

a case-by-case basis, exclude certain conditions of use, such as de minimis uses, from the scope of risk evaluations?

- b. Even if EPA's nonbinding preamble discussion is reviewable, was it nonetheless reasonable and permissible under TSCA?
3. Petitioners agree that EPA may issue early risk determinations for a particular condition of use for a chemical—while the risk evaluation for other uses of that chemical remains pending—if EPA determines that the condition of use poses unreasonable risks. Did EPA reasonably conclude that it can also issue early risk determinations for particular conditions of use when EPA concludes that it poses no unreasonable risk?
4. The Rules include provisions outlining how EPA will gather and consider information related to risk evaluations. EPA has moved to voluntarily remand three of the challenged provisions. Have Petitioners met their burden to show that EPA erred in the remaining two provisions?
5. Petitioners seek vacatur of numerous provisions of the Rules and their preambles, despite raising no arguments as to some of them and no basis for vacatur of the rest. Have Petitioners waived their requests for vacatur?

### **PERTINENT STATUTES AND REGULATIONS**

All pertinent statutes and regulations are contained in either the addendum to Petitioners' opening brief or the addendum to this brief.

## STATEMENT OF THE CASE

### A. Introduction

EPA's Inventory lists over 80,000 chemical substances that have been manufactured or processed in the United States since the late 1970s. Chemicals serve numerous roles in our lives and range from zinc oxide, an ingredient in many "natural" sunscreens, to perchloroethylene, a component of many dry-cleaning products that must be handled carefully. While many chemicals are innocuous, others pose risks to human health or the environment.

In 2016, Congress amended the Toxic Substances Control Act (TSCA or Act), creating, among other things, a triage process requiring EPA to systematically prioritize chemicals based on their potential to present risks under their conditions of use, evaluate the risks of high-priority chemicals, and ultimately regulate to remove any unreasonable risks EPA identifies.

These consolidated cases involve two foundational rulemakings specifying how EPA will conduct the first two steps in the triage process: prioritization and risk evaluation. Petitioners challenge three aspects of these Rules and their preambles related to how EPA intends to focus the risk evaluation process. First, EPA interpreted TSCA as granting it discretion to determine what conditions constitute a chemical's "conditions of use," and to generally exclude legacy activities—i.e., primarily historical activities that do not involve ongoing or prospective manufacture, processing, or distribution in commerce of a chemical substance as a product. This

interpretation was based on statutory text, the limited authority that EPA has under TSCA to ultimately regulate such activities, and recent legislative history. Second, the Risk Evaluation Rule requires EPA to issue a scope document for each risk evaluation. The preamble further includes a nonbinding and equivocal discussion of potentially excluding certain conditions of use from scope documents when appropriate, such as when a use is de minimis. Third, the Risk Evaluation Rule specifies that EPA may issue risk determinations on various conditions of use for the same chemical in one or multiple documents. To the extent these claims are reviewable, EPA reasonably interpreted its authority based on the statutory text, the scheme created by Congress, and legislative history. However, this court does not have jurisdiction over EPA's preamble discussion of things it may do on a case-by-case basis at a future time.

Petitioners also challenge certain information-gathering and consideration provisions. EPA is concurrently seeking voluntary remand of three of these, and Petitioners' claims regarding the rest lack merit. These petitions should be denied.

#### **B. The Toxic Substances Control Act and Its Recent Amendments**

In 1976, Congress enacted TSCA to prevent the unreasonable risks associated with certain chemical substances. *See* 15 U.S.C. §§ 2601-97. The Act was designed to facilitate review and, if necessary, regulation of such chemicals. S. Rep. No. 94-698, at 5 (1976), *reprinted in* Legislative History of TSCA at 161; H.R. Rep. No. 94-1341, at 1, 6 (1976), *reprinted in* Legislative History of TSCA at 409, 414 (Comm. Print 1976).

Congress required EPA to maintain an Inventory of chemical substances manufactured or processed in the United States and provided EPA discretionary authority for their review and regulation. 15 U.S.C. §§ 2604, 2606(a). However, Congress determined that, as originally enacted, TSCA did not achieve its aim due to a variety of procedural and substantive complications. 162 Cong. Rec. S3511-01 (daily ed. June 7, 2016) at S3513 (discussing barriers to chemical testing), S3516 (discussing previous requirement for EPA to consider cost), S3516 (discussing “grandfathering” of chemicals on the TSCA Inventory).

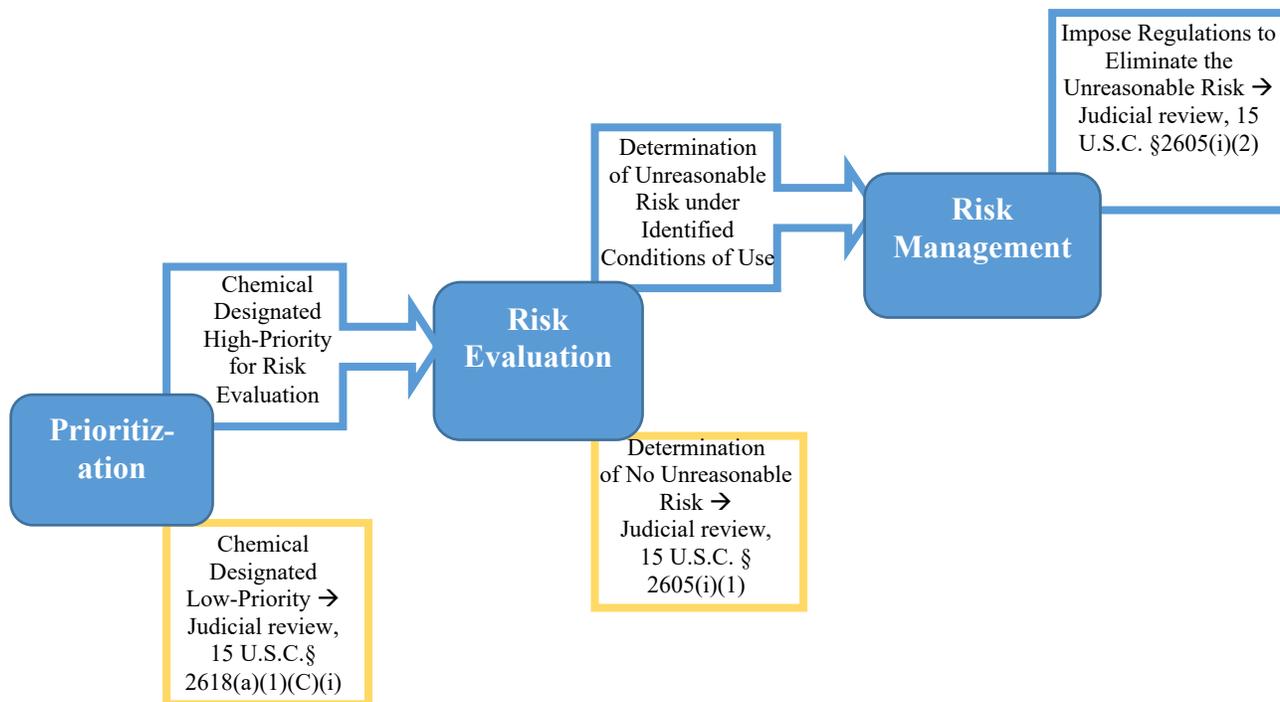
In 2016, Congress amended TSCA through the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“Lautenberg Act”). Pub. L. No. 114-182 (June 22, 2016). This “set[] in motion a process under which EPA will for the first time systematically review the safety of chemicals in active commerce,” while enabling EPA to focus on “priority chemicals” and “conditions of use that raise the greatest potential for risk.” 162 Cong. Rec. at S3516 col. 3, S3519 col. 3.

Congress created a three-step triage process that requires EPA to assess existing chemicals most likely to pose risks and then to quickly issue regulations to mitigate unreasonable risks. First, EPA must “prioritize” individual chemicals as either low- or high-priority based on the chemical’s “conditions of use,” a defined term of art. 15 U.S.C. §§ 2602(4), 2605(b)(1). A low-priority designation ends the process for a chemical and is subject to judicial review. *Id.* § 2618(a)(1)(C)(i).

Second, high-priority chemicals (as well as certain substances that skip prioritization) move on to the “risk evaluation” phase. *Id.* § 2605(b)(2)(A)-(B). Here, EPA must publish a “scope” document that includes the hazards, exposures, conditions of use, and potentially exposed or susceptible subpopulations for each chemical that EPA expects to consider. *Id.* § 2605(b)(3)(A), (4)(D). EPA then must determine whether the chemical poses an unreasonable risk to human health or the environment under the conditions of use included within the scope of the risk evaluation. *Id.* § 2605(b)(4)(A). A finding that a chemical poses no unreasonable risk ends the process and is subject to judicial review. *Id.* §§ 2605(i)(1), 2618(a)(1)(A).

Third, a chemical deemed to pose an unreasonable risk under any of its conditions of use moves to the “risk management” phase. *Id.* § 2605(a)(1). EPA must impose requirements on the chemical as necessary to remove the unreasonable risk. The risk management decision, including the unreasonable risk determination, is subject to judicial review. *Id.* §§ 2605(i)(2), 2618(a)(1)(A).

Graphically, the process flow looks like this:



Congress imposed strict requirements for the pace of evaluations. By December 2016, EPA had to begin risk evaluations on 10 chemical substances that were excused from prioritization. *Id.* § 2605(b)(2)(A). Starting at the end of 2019, EPA must have designated at least 20 low-priority substances and must have at least 20 risk evaluations for high-priority chemicals ongoing at any one time. *Id.* § 2605(b)(2)(B), (3)(C). Each risk evaluation must normally be completed within three years. *Id.* § 2605(b)(4)(G). Regulations must normally be finalized within two years of a final risk evaluation finding unreasonable risk. *Id.* § 2605(c)(1)(B).

### C. The Prioritization Rule and the Risk Evaluation Rule

This case involves two regulations—the Prioritization Rule and the Risk Evaluation Rule—establishing procedures EPA will use for the first two phases of the

triage process. Under the Prioritization Rule, EPA will: (1) select candidate chemical substances based on hazard and exposure potential and conduct a screening review based primarily on the chemical's properties and conditions of use; and (2) designate the chemical as low- or high-priority. 40 C.F.R. §§ 702.5, 702.7, 702.9, 702.11; 82 Fed. Reg. at 33,763-64 (ER 39-40). Then, for high-priority chemicals, under the Risk Evaluation Rule, EPA will: (1) issue a "scope" document specifying, among other things, the conditions of use that EPA expects to consider; (2) assess the hazards and likely exposure pathways of the chemical; (3) characterize the chemical using the best available science; and (4) issue a risk determination, all of which will be subject to public comment. 40 C.F.R. § 702.41, 702.43, 702.47; 82 Fed. Reg. at 33,750-52 (ER 25-27). Upon determination that a chemical poses unreasonable risks under any of its conditions of use, EPA will initiate the third and final step in the process: a risk management regulation to remove the identified risk. 40 C.F.R. § 702.49; 82 Fed. Reg. at 33,752-53 (ER 27-28).

Three aspects of the Rules and their preambles involving how EPA focuses its review are at issue in this case. Some of these are regulatory provisions and statutory interpretations; others merely discuss actions EPA may take on a case-by-case basis.

The first aspect is EPA's interpretation of "conditions of use" under the Act. TSCA defines the phrase as "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C.

§ 2602(4). In the final Rules, EPA determined that TSCA did not mandate inclusion of “all” activities associated with a chemical as conditions of use. 82 Fed. Reg. at 33,728-29 (ER 3-4). Rather, EPA interpreted the phrase as referring to ongoing and prospective activities and requiring the exercise of some discretion as well as a factual determination of what circumstances constitute each chemical’s conditions of use. *Id.*

EPA interpreted the Act’s text, in light of the Act’s structure and legislative history, as focused on the prospective and ongoing flow of chemicals in commerce. *Id.* In other words, EPA considers TSCA’s triage scheme to be the “tap” through which chemicals flow from manufacture into use. Thus, EPA interpreted the phrase “conditions of use” to exclude certain categories of activities. *Id.* One of these is the intentional misuse of chemicals. *Id.* The others are legacy activities, including legacy uses (activities with no ongoing or prospective manufacturing, processing, or distribution) and their associated disposal (future disposal from legacy uses), and legacy disposal (disposal that occurred in the past resulting in chemicals currently in places like landfills). *Id.* at 33,729-30 (ER 4-5). EPA considered, among other things, the tools that Congress gave it to ultimately regulate such activities during the risk management phase. *Id.* at 33,730 (ER 5). Because EPA has limited and, under some circumstances, no authority to regulate legacy activities under section 6(a), EPA believed that Congress did not intend it to determine whether such activities pose an unreasonable risk that EPA would be required to regulate. *Id.* at 33,730 (ER 5). Without such exclusions, the concept of conditions of use would render risk

evaluations unmanageable—an outcome EPA did not believe Congress intended. *Id.* at 33,728-30 (ER 3-5); 82 Fed. Reg. at 33,755 (ER 31). However, as EPA noted, EPA may still consider legacy activities as part of individual risk evaluations insofar as they contribute to background exposure or where they can inform the potential risks of non-legacy activities. 82 Fed. Reg. at 33,730 (ER 5).

The second aspect of the Rules at issue involves the scope of risk evaluations. In the first six months of the risk evaluation process, TSCA requires EPA to identify in a “scope” document “the conditions of use . . . that the Administrator expects to consider.” 15 U.S.C. § 2605(b)(4)(D). The Risk Evaluation Rule accordingly states that scope documents will include “the condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.” 40 C.F.R. § 702.41(c)(1). The preamble to the Risk Evaluation Rule also discusses the possibility that EPA “may” “on a case-by-case basis, exclude certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern.” 82 Fed. Reg. at 33,729 (ER 4). Some examples of conditions of use that EPA “may” exclude “on a case-by-case basis” include circumstances that present only “de minimis” risks, such as uses that occur in a closed system that precludes exposure, or those that have been adequately assessed and managed by another agency. *Id.* However, EPA explained that it would be “premature to definitively exclude a priori specific conditions of use from risk evaluations” at this time because such determinations would be highly fact-

specific. 82 Fed. Reg. at 33,730 (ER 5). Any excluded condition of use would be expressly identified, subject to public comment, and ultimately judicially reviewable. 82 Fed. Reg. at 33,729 (ER 4); 15 U.S.C. § 2605(i)(1)-(2).

The third aspect of the Rules at issue involves risk determinations for individual conditions of use. Once the process begins, EPA normally has only three years to determine whether a chemical poses an unreasonable risk. 15 U.S.C. § 2605(b)(4)(G). The Risk Evaluation Rule states that EPA will determine whether a chemical presents an unreasonable risk under every condition of use within the scope, “either in a single decision document or in multiple decision documents.” 40 C.F.R. § 702.47. So if EPA has sufficient information to determine that a chemical does or does not pose an unreasonable risk under a particular condition of use, EPA may publish an early determination for that particular condition of use, while the evaluation for the remaining conditions of use continues. 82 Fed. Reg. at 33,729 (ER 4). Any early determination would be subject to public comment and peer review as normal and would then be subject to judicial review. *Id.*; 15 U.S.C. § 2605(i)(1)-(2).

The Rules also prescribe the manner in which EPA gathers and considers information and the way in which information is to be submitted to the Agency. Relevant here, these include 40 C.F.R. §§ 702.5(e) (EPA will obtain information necessary to conduct prioritization before initiating the prioritization process), and 702.9(b) (when screening a chemical during prioritization, EPA will consider

information “consistent with the scientific standards . . . in 15 U.S.C. 2625(h)”), 702.31(d), 702.37(b)(4), and 702.37(b)(6).

#### **D. Procedural History**

Petitioners challenge each of the three aspects of the Rules discussed above involving how EPA focuses its review under the triage process, as well as each of the identified information-gathering provisions.

Concurrently with this brief, EPA is filing a motion for voluntary remand of three of the challenged information-gathering provisions: 40 C.F.R. §§ 702.31(d), 702.37(b)(4), and 702.37(b)(6), discussed in sections IV.A, IV.B, and IV.C of Petitioners’ brief. As explained in the motion, remand will serve the interests of judicial economy because EPA intends to administratively revisit the provisions that Petitioners challenge.

Also pending is Petitioners’ motion to “complete” the administrative records (Dkt. 43), filed the same day as their opening brief, April 16, 2018. As explained in EPA’s response (Dkt. 55), that motion seeks merely to distract the Court with non-record information that is not relevant to the questions before the Court and should be denied.<sup>3</sup> The Court should not consider the extra-record documents included in that motion, many of which are cited in Petitioners’ opening brief.

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<sup>3</sup> Indeed, Petitioners do not seriously argue that any of these documents is necessary for the Court to rule on their substantive challenges. Rather, they repeat allegations from their motion in the background section of their brief, referring to the

*Cont.*

## SUMMARY OF ARGUMENT

Prioritizations and risk evaluations are not actions EPA takes in the abstract; they are the first two steps in a triage process designed to ultimately lead to a third: regulations to remove any identified unreasonable risk. EPA’s Prioritization Rule and Risk Evaluation Rule reasonably take into account this ultimate goal and should be upheld.

First, Petitioners’ challenge to EPA’s interpretation of the definition of “conditions of use,” Pet’rs Br. Arg. III, fails because Congress gave EPA discretion to determine what circumstances meet the definition and EPA appropriately exercised its discretion. EPA reasonably determined that Congress intended it to focus on the prospective and ongoing flow of chemicals in commerce. This is reflected in the statutory text and in EPA’s limited regulatory tools under TSCA to remove unreasonable risks posed by legacy activities.

Second, Petitioners’ purported challenge to the scope provision in the Risk Evaluation Rule, Pet’rs Br. Arg. I, is impermissible as a matter of law. Petitioners’ challenge is not directed to the regulation EPA promulgated—which mirrors the

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“influence” of Dr. Nancy Beck, an EPA official, on the final rule. *See* Pet’rs Br. at 13-15. Petitioners evidently attempt to use these documents to cloud the Court’s view of EPA’s rulemaking process. Because Petitioners did not raise any procedural challenge to EPA’s rulemaking process in their opening brief, any such claim is waived. *See United States v. Kama*, 394 F.3d 1236, 1238 (9th Cir. 2005) (“[A]n issue is waived when the appellant does not specifically and distinctly argue the issue in [an] opening brief.”).

statutory text. Rather, Petitioners challenge EPA's preamble statements that EPA "may," on a case-by-case basis, exclude particular conditions of use from the scope of a chemical's risk evaluation when EPA has good reason, such as when a condition of use presents only de minimis exposure potential. This Court lacks jurisdiction to review such equivocal and nonbinding statements. They do not constitute reviewable final agency action and are not ripe for review. Additionally, Petitioners do not identify any non-speculative injury and therefore lack Article III standing for this claim. To the extent EPA's tentative preamble language is reviewable, Petitioners' challenge to the scope provision should also be rejected on the merits. EPA's discussion was consistent with the text and purpose of the Act.

Third, Petitioners' argument that EPA may only issue early risk determinations where it finds unreasonable risk, but not where it finds no unreasonable risk, during review of a chemical's other conditions of use, Pet'rs Br. Arg. II, is wholly unfounded. Nothing in the Act or Rules requires EPA to evaluate the risks of all included conditions of use in a single document.

As to Petitioners' challenges to Rule provisions governing EPA's information gathering and consideration, Pet'rs Br. Arg. IV, EPA is seeking voluntary remand of three of the provisions. Petitioners' challenge to the remaining information-gathering provisions are without merit.

## STANDARD OF REVIEW

Jurisdiction is a “threshold issue”: if subject matter jurisdiction does not exist for a particular claim, “the court cannot proceed at all” as to that claim. *Steel Co. v. Citizens for a Better Env’t*, 523 U.S. 83, 94 (1998). Petitioners bear the burden of demonstrating subject matter jurisdiction. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994).

On the merits, with limited exceptions not applicable here, EPA rules promulgated under TSCA are reviewed under the Administrative Procedure Act (APA). 15 U.S.C. § 2618(c)(1)(B). “Under the APA, [this Court should] set aside an agency’s decision if it is ‘arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.’” *Nw. Coal. for Alts. to Pesticides v. EPA*, 544 F.3d 1043, 1047 (9th Cir. 2008) (citation omitted). The familiar arbitrary-or-capricious standard is highly deferential, presuming the validity of agency actions and upholding them if they satisfy minimum standards of rationality. *Kern Cty. Farm Bureau v. Allen*, 450 F.3d 1072, 1075-76 (9th Cir. 2006). “The scope of review under the ‘arbitrary and capricious’ standard is narrow and a court is not to substitute its judgment for that of the agency.” *Motor Vehicles Mfrs.’ Ass’n v. State Farm Mut. Auto Ins. Co.*, 463 U.S. 29, 43 (1983). The pertinent question is “whether the [agency’s] decision was based on a consideration of the relevant factors and whether there has been a clear error of judgment.” *Id.* at 42-43 (internal quotation marks and citation omitted).

Questions of statutory interpretation are governed by the two-step test set forth in *Chevron, U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837, 842-45 (1984). In the first step, the reviewing court determines whether Congress spoke to the precise question at issue. If so, the inquiry ends. If the statute is silent or ambiguous on the relevant point, the court must determine whether the agency's interpretation is based on a permissible construction of the statute and, if so, defer to it. *Id.* The agency's interpretation need not represent the only permissible reading of the statute, nor the reading that the Court might have given it. *Id.* at 843 & n.11; *see also Leslie Salt Co. v. United States*, 55 F.3d 1388, 1394 (9th Cir. 1995). Additionally, where Congress delegates discretionary authority to "fill" statutory gaps, the Court "give[s] the resulting regulation controlling weight unless it is manifestly contrary to the statute." *San Bernardino Mountains Cmty. Hosp. Dist. v. Sec'y of Health & Human Servs.*, 63 F.3d 882, 887 (9th Cir. 1995) (internal quotation marks and citation omitted).

## ARGUMENT

### **I. EPA Reasonably Exercised Its Discretion to Determine That Legacy Activities That EPA Has Limited Tools to Ultimately Regulate Should Not Form the Basis for Findings of Unreasonable Risk.**

EPA interpreted the phrase "conditions of use" as generally applying to circumstances under which chemicals flow from manufacture, processing, and distribution in commerce into the use and disposal stages of their lifecycle rather than as requiring EPA to reach back in time. *See* 82 Fed. Reg. at 33,729-30 (ER 4-5). In light of the prospective focus and triage goals of the Act, this was a reasonable

exercise of EPA's discretion consistent with Congressional intent. Petitioners' argument under *Chevron* step one that the statute compels EPA to treat legacy use, associated disposal, and legacy disposal as conditions of use (Pet'rs Br. Arg. III, at 40-51) is unsupported by the Act. To the extent Petitioners argue that EPA's interpretation was unreasonable under *Chevron* step two, their claim also fails because EPA reasonably took into account the Act's goals and structure.

**A. TSCA Plainly Confers Discretion on EPA to Determine What Constitutes a Chemical's Conditions of Use and Is Ambiguous as to How Legacy Activities Should Be Treated.**

“The starting point in every case involving construction of a statute is the language itself.” *Blue Chip Stamps v. Manor Drug Stores*, 421 U.S. 723, 756 (1975) (Powell, J., concurring). Here, the statutory definition of conditions of use—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”—is generally focused on current and future activities. 15 U.S.C. § 2602(4). “[I]ntended” and “reasonably foreseen” are plainly forward looking terms. “[T]o be” is an infinitive that, when combined with the preceding “is known” becomes a present tense verb. So Congress intended EPA to focus on activities for which manufacturing, processing or distribution in commerce is intended, known or reasonably foreseen to occur. With over 80,000 chemicals on the Inventory, this alone is a gargantuan task. But the Act does not resolve the question of whether, as Petitioners contend, Congress also intended EPA

to evaluate every circumstance wherein chemicals exist in the environment in some way. Such an additional task could ultimately swallow all of EPA's resources and impede its ability to evaluate ongoing and prospective activities.

Additionally, the language leaves EPA broad discretion to determine what constitutes a condition of use. Congress sometimes delegates an agency discretion by leaving gaps to be filled, signalling that significant deference to the agency is warranted. *San Bernardino Mountains*, 63 F.3d at 886. Statutory ambiguity on a particular question also indicates that Congress intended to confer broad discretion and takes the matter out of *Chevron* step one. See, e.g., *Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208, 222-23 (2009) (statutory silence demonstrated Congress' intent to confer greater discretion on EPA); *Chevron*, 467 U.S. at 842-45.

Here, the statutory definition of conditions of use expressly confers discretion. 15 U.S.C. § 2602(4). “[T]his is not a statute as to which we can only infer, from Congress’ silence, an implicit intent to delegate to the [Administrator] the authority to reasonably interpret the statutory terms.” *Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1025 (D.C. Cir. 2000). Instead, it signals discretion in plain terms: “as determined by the Administrator.” 15 U.S.C. § 2602(4). This is the sort of classic language Congress uses to indicate that an agency is expected to fill the gaps, make a finding, and exercise judgment. *Nat. Res. Def. Council v. EPA*, 526 F.3d 591, 595 n.4 (9th Cir. 2008) (conference report stating that permits are not required where runoff is not contaminated “as determined by the Administrator” “gives the EPA administrator

discretion to determine when contamination has occurred” (internal quotation marks and citation omitted). *San Bernardino Mountains*, 63 F.3d at 886 (“We find the statute’s inclusion of the terms ‘such as’ and ‘as determined by the Secretary,’ [as a] broad grant of discretionary authority.”) (citation omitted); *Transitional Hosps.*, 222 F.3d at 1026 (by using the “parenthetical phrase, ‘as determined by the Secretary’ . . . Congress has made an express delegation of authority to the agency” that “takes the case out of the realm of *Chevron* step one[.]”) (citation omitted). Additionally, “intended,” “known,” and “reasonably foreseen” are broad, general terms that plainly require EPA to exercise its judgment. *E.g., Am. Fed’n of Labor & Cong. of Indus. Orgs. v. Chao*, 409 F.3d 377, 393 (D.C. Cir. 2005) (similarly broad term “necessary” “clearly invites further definition”).

Congress obviously did not mean for EPA to consider every circumstance that could conceivably exist to be a chemical’s conditions of use because that would undermine the Act’s triage process. *See Catawba Cty., Inc. v. EPA*, 571 F.3d 20, 35 (D.C. Cir. 2009) (statute’s text, structure, and purpose are all relevant to whether a statute is ambiguous). As EPA correctly reads the Act, it “largely [requires] a factual determination—i.e., EPA is to determine whether a chemical substance is actually involved in one or more of the activities listed in the definition”—but it will also “inevitably involve the exercise of some discretion.” 82 Fed. Reg. at 33,729 (ER 4). In other words, EPA must determine both what circumstances of a chemical’s manufacture, processing, distribution, use, or disposal Congress intended EPA to

consider and factually which of a chemical's circumstances are involved in those activities. *See id.*; *Am. Fed'n of Labor & Cong. of Indus. Orgs.*, 409 F.3d at 393 (statute requiring Secretary's determination distinct from merely requiring a factual finding and "fairly exudes deference" (internal quotation marks and citation omitted)).

For example, suppose EPA is aware that teenagers have deliberately inhaled compressed air. The Act does not specify whether intentional misuse is a "use" that constitutes a condition of use for chemicals in a compressed air can. Indeed, Congressional statements say explicitly that EPA was expected to exclude certain categories such as "'intentional misuse' of chemicals" from conditions of use. S. Rep. 114-67, at 7 (2015).

As for the specific question at issue here—how EPA is to treat legacy activities wherein chemicals are not involved in prospective or ongoing manufacture, processing, or distribution of the chemical as a product—the statute leaves it unanswered.

The term "use" in the statutory definition does not, as Petitioners insist, resolve the question regarding legacy use. "Use" could mean the act of deploying something into the environment, or, as Petitioners prefer, it could refer to anything that exists in the world that is still useful in some way. The dictionary supports either definition. *See Merriam-Webster*, [https://www.merriam-webster.com/dictionary/use?utm\\_campaign=sd&utm\\_medium=serp&utm\\_source=jsonld](https://www.merriam-webster.com/dictionary/use?utm_campaign=sd&utm_medium=serp&utm_source=jsonld) (defining "use" as "the act or practice of employing something" and "the fact or

state of being used”). Nothing in the term itself either compels or rules out one definition over the other. *See also Dolan v. U.S. Postal Serv.*, 546 U.S. 481, 486 (2006) (“The definition of words in isolation ... is not necessarily controlling in statutory construction”).

Petitioners are similarly incorrect that the phrase “disposed of” compels EPA to conclude that associated disposal or legacy disposal are the kinds of disposal that constitute conditions of use. *See* Pet’rs Br. at 43-44. “[D]isposed of” could mean the act of putting something in a landfill or other resting place, or it could conceivably refer to the movement of chemicals by natural forces after the initial act of disposal. *See* Merriam-Webster, <https://www.merriam-webster.com/dictionary/dispose> (defining “dispose” as “to put (someone or something) in a particular position or place”). Petitioners point to EPA’s broader uses of the term “disposal” for specific prohibitions under TSCA section 6(e) of the toxic chemical polychlorinated biphenyl under 40 C.F.R. pt. 761 subpt. A, Pet’rs Br. at 43, but that regulation was issued before the recent TSCA amendments and says nothing about whether the *statutory term* is ambiguous. An interpretation by EPA in one context does not mean that Congress *required* EPA to interpret the term in the same manner in another.

Also indicating ambiguity, both “use” and “disposal” are part of a list that includes more specific activities involving chemicals in active commerce—i.e., manufacture, processing, and distribution—suggesting that these terms might be more narrowly applied. *See Dole v. United Steelworkers of Am.*, 494 U.S. 26, 36 (1990)

(Under the “traditional canon of construction, *noscitur a sociis*, . . . words grouped in a list should be given related meaning.” (internal quotation marks and citation omitted)).

And the Act provides only limited tools for regulating legacy activities during the risk management phase, 15 U.S.C. § 2605(a), suggesting that Congress was not focused on the mere existence of chemicals in the environment. *See King v. St. Vincent’s Hosp.*, 502 U.S. 215, 221 (1991) (restating “cardinal rule that a statute is to be read as a whole . . . since the meaning of statutory language, plain or not, depends on context”) (citation omitted). To illustrate the ambiguity, consider a couch with a flame retardant coating that is no longer, and is not “reasonably foreseen” to be, manufactured, processed, or distributed in commerce for that use. The couch may still exist in the environment. But EPA lacks authority in the risk management phase to prohibit residential or other non-commercial actors from continuing to sit on the couch or have it in their homes. *See* 15 U.S.C. § 2605(a)(5) (authorizing only regulation of commercial uses). While EPA could potentially issue regulations governing homeowners who “dispose[] of” the couch, EPA’s tools for doing so are limited to disposal “for commercial purposes.” *Id.* § 2605(a)(6)(A). If EPA were to treat the historical couch coating as a condition of use for the chemical in question, then EPA would have to prioritize the chemical based on the couch coating circumstance, 15 U.S.C. § 2605(b)(1), determine whether to include it in the scope of the risk evaluation and, if so, whether it poses an unreasonable risk, *id.* § 2605(b)(4)(A), and then regulate it in a manner that removes any identified

unreasonable risk, *id.* § 2605(a)(1). But under these facts, EPA could not meet the clear obligation to eliminate the identified unreasonable risk because it has imperfect tools under TSCA to do so. *Id.* § 2605(a).

Petitioners argue at length that the Act is unambiguous. Nowhere do they acknowledge that the Act confers any discretion on EPA to determine what precise circumstances constitute conditions of use. Pet’rs Br. at 41-44. In their view, EPA may only make a factual determination as to whether a chemical is associated with any of the activities listed in the statutory definition. But that position ignores the necessary judgment calls involved in making a factual determination and reads the phrase “as determined by the Administrator” out of the Act.<sup>4</sup> *See, e.g., Transitional Hosps.*, 222 F.3d at 1026 (deference conferred by phrase “as determined by the Secretary” “takes the case out of the realm of *Chevron* step one[]”); *Bd. of Trustees of Leland Stanford Junior Univ. v. Roche Molecular Sys., Inc.*, 563 U.S. 776, 788 (2011) (Court has a “general reluctan[ce] to treat statutory terms as surplusage” (internal quotation marks and citation omitted)). Petitioners also suggest that Congress may only confer discretion by using the word “discretion” in the statute. Pet’rs Br. at 27-28. This

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<sup>4</sup> The position is odd because a Petitioner comment letter acknowledges that EPA may categorically exclude intentional misuse as a condition of use. Comments of the Environmental Defense Fund on Procedures for Chemical Risk Evaluation under the Amended Toxic Substances Control Act Proposed Rule 13 (Mar. 20, 2017) (SER 811). If EPA has discretion to categorically exclude one type of activity as a condition of use, it follows that EPA has discretion to consider and exclude others so long as doing so is also consistent with the statutory goals.

assertion is belied by blackletter law, *see Natural Resources Defense Council*, 526 F.3d at 595 n.4 (phrase “as determined by the Administrator” confers discretion on EPA), and by the plain text of numerous other TSCA provisions, *see infra* Argument II.C.1. Petitioners’ *Chevron* step one argument must be rejected.

**B. EPA Reasonably Interpreted the Statutory Phrase “Conditions of Use” to Exclude Activities It Has Limited Tools to Regulate Under TSCA.**

In the absence of clear statutory direction, EPA reasonably exercised its discretion to fill the gaps by interpreting the phrase “conditions of use” to require it to evaluate the ongoing and prospective flow of chemicals in commerce. 82 Fed. Reg. at 33,729-30 (ER 4-5). That is, EPA reads the phrase as focusing on the continuing flow of chemical substances from manufacture, processing, and distribution in commerce into the use and disposal stages of their lifecycle, but not requiring EPA to address potential risks associated with chemicals already in the environment. *Id.*

EPA focused heavily on the statutory context and goals, including the limits to EPA’s regulatory authority under section 6(a), 15 U.S.C. § 2605(a). 82 Fed Reg. at 33,730 (ER 5). A critical purpose of the Act is for EPA to identify and evaluate chemicals posing unreasonable risks and to regulate to remove the unreasonable risks. *See* 15 U.S.C. § 2605. But, as Petitioners fail to acknowledge, *see, e.g.,* Pet’rs Br. at 47-50, EPA’s authority to regulate the non-commercial use and disposal of a chemical, which is likely to be a significant portion of legacy activities, is limited. *See* 15 U.S.C. § 2605(a)(5)-(6). EPA can regulate disposal of a chemical “by its manufacturer or

processor or by any other person who uses, or disposes of it, for commercial purposes,” for example. *Id.* § 2605(a)(6). That authority, however, is limited for both associated disposal (e.g., disposal of a treated couch by a residential consumer) and legacy disposal (e.g., disposal that occurred in the past that has led to chemicals in groundwater or landfills). *Id.* EPA also noted the Act’s tight statutory deadlines. EPA explained that it would frustrate the statutory goals to spend its limited resources evaluating activities it has limited or no authority to regulate. 82 Fed Reg. at 33,730 (ER 5). This makes sense given the process embodied in section 6 and EPA’s extensive tools to regulate chemical manufacturers and other commercial actors. *See* 15 U.S.C. § 2605(a)(1)-(6).

Petitioners raise no plausible argument that EPA’s construction is inconsistent with the Act. *See Nat’l Ass’n of Clean Air Agencies v. EPA*, 489 F.3d 1221, 1230 (D.C. Cir. 2007) (EPA construction entitled to great deference unless contrary to Act). Petitioners argue that it is irrelevant that EPA lacks the tools to effectively regulate legacy activities because, under section 9(a), 15 U.S.C. § 2608(a), EPA may refer an unreasonable risk to another agency that has authority to regulate it. Pet’rs Br. at 50. But the section 9 process does not resolve the conundrum, because: (1) referral is only available when EPA determines that another agency *can* effectively control a risk; (2) that agency could decline to regulate; and (3) EPA is still required to regulate unreasonable risks if the other agency does not act within the specified timeframes. *See* 15 U.S.C. § 2608(a)(1), (4). If EPA refers a risk that EPA cannot regulate and then

the other agency does not act on time, then EPA would still find itself in the absurd position of being simultaneously required to regulate while lacking authority to do so. *See Griffin v. Oceanic Contractors, Inc.*, 458 U.S. 564, 575 (1982) (“[I]nterpretations of a statute which would produce absurd results are to be avoided if alternative interpretations consistent with the legislative purpose are available.”).

Petitioners argue that EPA’s interpretation is inconsistent with the statutory scheme because section 6 refers to “chemical substances” while section 8(b) requires EPA to distinguish “active” substances from “inactive” substances. Pet’rs Br. at 45-46. In their view, section 6 was intended to capture both active and inactive chemical substances, as well as legacy activities of both types of chemicals. But harmonization between the two sections is impossible due to the differences in purpose and scope. Under section 8(b), EPA must maintain an Inventory of chemicals “manufactured or processed in the United States,” which is relevant primarily to the process under section 5: if a chemical is not on the Inventory, someone wishing to manufacture it must go through the section 5 approval process for new chemicals. 15 U.S.C. §§ 2607(b), 2604(a)(1)(A)(i). Under section 8(b)(4), EPA must update the Inventory as to whether the chemicals on it are active or inactive, meaning whether they were “manufactured or processed” between 2006 and 2016. *Id.* § 2607(b)(4). Section 6 is not limited to chemicals manufactured or processed between 2006 and 2016. *Id.* §§ 2602(4) (conditions of use include, for example, circumstances “intended” and “reasonably foreseen” to be manufactured or processed), 2605(b)(1) (treatment of

chemicals under section 6 restricted only by their conditions of use, as determined by the Administrator). And while EPA may find the Inventory useful when identifying *chemicals* for prioritization under section 6, it provides no help in determining what constitutes that chemical's conditions of use. *See, e.g.*, 15 U.S.C. § 2605(b)(1). Thus, any clues from section 8(b) cannot overcome the contrary evidence that Congress intended EPA to focus on the prospective and ongoing flow of chemicals in commerce. Petitioners fail to show that EPA's decision to exclude legacy activities from the definition of conditions of use is manifestly contrary to the statute. *See San Bernardino Mountains*, 63 F.3d at 887.

**C. Recent Legislative History Supports EPA's Approach to Focus on Quickly Regulating the Worst Risks.**

Legislative history can “shed new light on congressional intent, notwithstanding statutory language that appears superficially clear.” *Nat. Resources Def. Council v. EPA*, 489 F.3d 1250, 1259 (D.C. Cir. 2007) (internal quotation marks and citation omitted). Here, the legislative history is both recent and informative.

In a section entitled “Congressional Intent Behind Specific Provisions of the Bill,” the Congressional Report on the Lautenberg Act includes the following from Senator Vitter, one of the primary authors and negotiators of the policy:

[T]he Agency is given the discretion to determine the conditions of use that the Agency will address in its evaluation of the priority chemical. This assures that the Agency's focus on priority chemicals is on conditions of use that raise the greatest potential for risk. This also assures that the Agency can effectively assess

and control priority chemicals and meet the new law's strict deadlines.

162 Cong. Rec. at S3519 col. 3. This uncontested history indicates the primary authors in Congress intended to give EPA discretion over conditions of use and to enable EPA to focus its efforts where they can best be spent.

The legislative history also includes numerous references to TSCA's purpose in regulating "chemicals in commerce," "chemicals already on the market," and chemicals that are being actively manufactured. *E.g.*, H.R. Rep. No. 114-176, at 12 (2015), *reprinted in* 2016 U.S.C.C.A.N. 276, 277 (TSCA described as "legislation to identify and control potentially dangerous chemicals in U.S. commerce"); S. Rep. No. 114-67, at 2 (2015) (TSCA's "unique focus is on industrial chemicals in commerce"); *id.* at 4 (pre-amendment TSCA flawed because it lacked a requirement "to systematically assess existing chemicals in commerce"); *id.* at 11 ("In general, EPA is to focus the prioritization screening process on chemicals that are in active commerce."); *id.* at 13 ("Committee's objective" is to "address[] the backlog of unassessed chemicals in commerce"); 162 Cong. Rec. at S3516, col. 3 (Detailed Analysis and Additional Views of Democratic Members) ("[t]he goal of the legislation is to ensure that all chemicals on the market" get a systematic safety review); U.S. Senate Environment and Public Works Committee: "Reforming the Toxic Substances Control Act" at 2 ("TSCA is designed to regulate chemical substances that are being used to make millions of everyday products and materials."); *id.* at 3 ("All chemicals in

commerce will be reviewed for safety through a risk-based process.”). These strongly support EPA’s focus on ongoing and prospective activities. EPA reasonably considered this to mean that Congress did not intend for EPA to spin its wheels assessing historical activities in which chemicals are no longer flowing through active commerce as a product.

**D. Historical Activities May Still Factor into EPA’s Analysis as Background Exposure.**

Much of Petitioners’ argument seems based on the idea that chemicals existing in the environment through legacy activities might still provide exposure pathways relevant to whether the chemical, as a whole, poses an unreasonable risk. Pet’rs Br. at 47-48. EPA agrees, and explained that “in a particular risk evaluation, EPA may consider background exposures from legacy use, associated disposal, and legacy disposal as part of an assessment of aggregate exposure or as a tool to evaluate the risk of exposure resulting from non-legacy uses.” 82 Fed. Reg. at 33,730 (ER 5). In other words, using Petitioners’ lead pipe example, if a subpopulation is getting a regular dose of lead exposure from pre-existing lead pipes, such exposure might be relevant to whether a lead-based toy would pose an unreasonable risk if allowed to be distributed in commerce. So while EPA’s interpretation of “conditions of use” excludes legacy activities as circumstances upon which EPA must prioritize chemicals, it does not mean that EPA will not consider legacy activities where appropriate. This is reasonable in light of the Act.

## II. Petitioners' Challenge to the Risk Evaluation Rule's Scope Provisions and Preamble Discussion Fails.

Petitioners' purported challenge (Pet'rs Br. Arg I, at 21-38) to the provision in the Risk Evaluation Rule outlining how EPA will draft risk evaluation scope documents, 40 C.F.R. § 702.41(c)(1), dramatically misreads the Rule and record. Petitioners contend that the Rule itself give EPA "carte blanche" to exclude any condition of use it chooses from the scope of a risk evaluation.<sup>5</sup> Pet'rs Br. at 22, 70. Petitioners' claim primarily stems from EPA's discussion in the preamble to the Rule of the possibility of case-by-case exclusions using conditional, equivocal, and nonbinding language. Pet'rs Br. Arg I, at 22, 26-28, 33, 35-36, 38; *id.* at 69-70 (requesting vacatur of preamble sections). But such nonbinding preamble statements are unreviewable. *Nat. Resources Def. Council v. EPA*, 559 F.3d 561, 564-65 (D.C. Cir.

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<sup>5</sup> Petitioners ask the Court to vacate the conditions of use scope provision, 40 C.F.R. § 702.41(c)(1), as well as others outlining procedures not challenged here but simply referring to "the conditions of use within the scope of the evaluation," including 40 C.F.R. §§ 702.41(a)(5), (a)(7), (a)(8), (a)(9), (c)(4)(i), (c)(4)(iii), and (d)(2); and 702.49(b), (c), and (d). Pet'rs Br. at 22, 70. For example, section 702.41(a)(5) states that EPA will ensure that all supporting analyses and components of a risk evaluation are well-tailored to the problems at hand. Petitioners present no basis for vacating these provisions in their entirety. Petitioners also purport to challenge sections 702.37(b)(3) and (e)(3) and assert in passing that these provisions allow EPA to limit a manufacturer-requested evaluation to the conditions of use identified by the manufacturer. Pet'rs Br. at 22. This is inaccurate. Section 702.37(b)(3) specifies the procedure for *manufacturers*, not EPA. And section 702.37(e)(3) expressly states that EPA will assess which additional conditions of use warrant inclusion in the scope and will treat the chemical in the same manner as substances designated high-priority.

2009) (“NRDC”).<sup>6</sup> And even if this Court were to reach such statements, EPA’s discussion of future possibilities is based on a permissible reading of TSCA.

**A. The Risk Evaluation Rule’s Provision on Scope Documents Mirrors the Statutory Text and Does Not Grant EPA the Authority Petitioners Claim.**

Petitioners argue that the scope provision in the Risk Evaluation Rule “grant[s]” EPA “unfettered discretion” to exclude any condition of use it chooses. Pet’rs Br. at 21-22. In fact, the scope provision is narrow and does no such thing.

The regulatory text of the scope provision is simple and straightforward: the scope of a risk evaluation will include, among other things, “the condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation.” 40 C.F.R. § 702.41(c)(1). This language closely mirrors the statutory text, which says that “[t]he Administrator shall . . . publish the scope of the risk evaluation to be conducted, including the hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations the Administrator expects to

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<sup>6</sup> EPA’s definitional interpretation of the phrase “conditions of use,” *see supra* Argument I, also appears solely in the preamble of the Rules and not in the regulations themselves. *Compare* 40 C.F.R. § 702.33 (mirroring 15 U.S.C. § 2602(4)) *with* 82 Fed. Reg. at 33,730 (ER 5). Unlike EPA’s conditional, equivocal, and nonbinding discussion of scope documents, however, EPA’s preamble interpretation regarding legacy activities is reviewable because it is a binding statutory interpretation that EPA stated it intends to apply going forward. *Kennecott Utah Copper Corp. v. U.S. Dep’t of Interior*, 88 F.3d 1191, 1222-23 (D.C. Cir. 1996) (preamble statements reviewable when it shows the agency “inten[ded] to bind either itself or regulated parties”); *NRDC*, 559 F.3d at 564-65.

consider.” 15 U.S.C. § 2605(b)(4)(D). In other words, TSCA requires EPA to issue a document stating what conditions of use EPA “expects to consider,” 15 U.S.C. § 2605(b)(4)(D), and the regulation merely confirms that EPA will do just that. Petitioners cannot credibly claim a distinction between “expects to consider” and “plans to consider” that invalidates the regulation on its face.

In a footnote, Petitioners argue that the regulatory text does more than the Act by asserting that, under the last antecedent rule, “expects to consider” refers only to the last item in the list, “potentially exposed or susceptible subpopulations,” and not to “conditions of use.” Pet’rs Br. at 35 n.7. However, Petitioners rely on the wrong canon of statutory interpretation. When a list is followed by a clause that *could* apply to all items in a list, the Supreme Court has held that the clause applies to all items in the list. *Paroline v. United States*, 134 S. Ct. 1710, 1720-21 (2014) (rejecting argument that “as a proximate result of the offense,” which appeared in a restitution statute after a list of types of losses, applied only to the last listed item); *Porto Rico Ry., Light & Power Co. v. Mor*, 253 U.S. 345, 348 (1920) (“When several words are followed by a clause which is applicable as much to the first and other words as to the last, the natural construction of the language demands that the clause be read as applicable to all.”). The Act means that EPA must describe in a scope document “the conditions of use . . . the Administrator expects to consider.” 15 U.S.C. § 2605(b)(4)(D).

Petitioners also support their claim of unfettered discretion by pointing to the Rule’s preamble where EPA suggested that it “may,” “on a case-by-case basis, exclude

certain activities that EPA has determined to be conditions of use in order to focus its analytical efforts on those exposures that are likely to present the greatest concern,” 82 Fed. Reg. at 33,729 (ER 4). Pet’rs Br. at 22, 26-28, 33, 35-36, 38. In the preamble, EPA also discussed specific types of things it “may” consider excluding, such as “de minimis” uses that occur in a closed system that precludes exposure or conditions of use that have been adequately assessed and managed by another agency. *Id.* Another possible example is a chemical’s presence as an impurity because it may be more appropriately evaluated with the substance the impurity appears in. *Id.* at 33,730 (ER 5). But nothing in the preamble requires that EPA actually exclude a condition of use from the scope.<sup>7</sup> Indeed, EPA expressly declined to commit, stating it would be “premature to definitively exclude a priori specific conditions of use from risk evaluations” at this time because any such determination would necessarily be highly fact-specific. *Id.* The preamble language does not appear in the regulation itself, and nothing in the Rule binds EPA or regulated parties in how the regulation will be applied in the future. *See Kennecott Utah*, 88 F.3d at 1222-23 (preamble statements

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<sup>7</sup> Petitioners’ brief points to non-final documents, on which Petitioners were invited to comment, for some of the 10 chemicals currently under review. Pet’rs Br. at 36-37. As explained in EPA’s opposition (Dkt. 55) to Petitioners’ motion to “complete” the administrative records, these documents are not part of the records on review here. Additionally, these scope documents identify only the conditions of use that EPA expects to consider in the risk evaluations, are subject to change and will be judicially reviewable as part of the final risk evaluations.

reviewable only when it shows that the agency “inten[ded] to bind either itself or regulated parties”).

**B. This Court Lacks Jurisdiction Over Petitioners’ Challenge to Conditional, Equivocal, and Nonbinding Preamble Statements That EPA “May” Exclude Uses from Risk Evaluations on a Case-by-Case Basis.**

The preamble statements that Petitioners take issue with are also not subject to judicial review. Only “final agency action” is judicially reviewable under the APA. 5 U.S.C. § 704; *see also Nat. Desert Ass’n v. U.S. Forest Serv.*, 465 F.3d 977, 982 (9th Cir. 2006) (finality is a jurisdictional requirement). Moreover, “hypothetical and non-specific” statements in a preamble to a rulemaking are not ripe for judicial review. *See, e.g., NRDC*, 559 F.3d at 565. And Petitioners do not have standing to challenge agency statements where there is no “concrete and particularized” “injury in fact” that is “not conjectural or hypothetical.” *Spokeo, Inc. v. Robins*, 136 S. Ct. 1540, 1547-48 (2016).

*1. The Preamble Statements Are Not Final Agency Action.*

First, nonbinding preamble statements in a Federal Register notice about how EPA “may” exercise its discretion on a case-by-case basis are not reviewable final agency action. Final agency action (1) “mark[s] the ‘consummation’ of the agency’s decisionmaking process,” and (2) is “one by which ‘rights or obligations have been determined,’ or from which ‘legal consequences will flow.’” *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997) (citation omitted).

These preambular statements do not mark the consummation of any process because EPA expressly declined to make any final decision “to definitively exclude a priori specific conditions of use from risk evaluations” or to “establish a specific test or restrictive definition to determine whether a condition of use is ‘reasonably foreseen.’” 82 Fed. Reg. at 33,730 (ER 5). EPA believed this “would be premature.” *Id.* Instead, EPA will have to make “reasonable, technically sound scoping decisions” or “develop additional scoping principles” “[a]s EPA gains experience in conducting risk evaluations.” *Id.* at 33,730-31 (ER 5-6); 15 U.S.C. § 2605(i)(1)-(2). *Those* decisions, in final risk evaluations, not EPA’s statements here, will be the consummation of a decisionmaking process.

Nor do the statements determine rights or obligations or have legal consequences. Neither EPA nor any affected person is legally bound by examples of how EPA “may” exercise its discretion in the future.<sup>8</sup>

The D.C. Circuit has held that preamble statements do not constitute binding, final agency action in nearly identical circumstances in *NRDC*, 559 F.3d at 564-65. There, EPA had issued a rule defining “exceptional events” using language that mirrored the Clean Air Act and then, in the preamble, provided examples of types of events that “may” qualify as exceptional events “on a case-by-case basis.” *Id.* at 562,

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<sup>8</sup> Even Petitioners acknowledge that preambular statements can be “non-binding.” Pet’rs Br. at 36.

564-65. Such statements were not final agency action because they were conditional (as evidenced by the word “may” instead of “will”), equivocal (as evidenced by the repeated assertion that exceptional events would be evaluated on a “case-by-case basis”), and nonbinding. *Id.* at 565.

Here, too, the Risk Evaluation Rule establishes a definition of “conditions of use” using the same language as TSCA. *Compare* 40 C.F.R. § 702.33 *with* 15 U.S.C. § 2602(4). The scope provision in EPA’s Risk Evaluation Rule is likewise nearly identical to that in the Act. *See supra* Argument II.A. Also, Petitioners attempt to challenge preamble statements that use the conditional word “may,” contain equivocal phrases like “case by case determination” and “highly fact-specific,” and explicitly do not bind the agency. 82 Fed. Reg. at 33,730 (ER 5). As in *NRDC*, these statements are simply not reviewable.

2. *Petitioners’ Challenge to Preamble Statements Is Not Ripe for Review.*

Second, these statements are not ripe for the same factual reason they are not final agency action. The ripeness question requires courts to “evaluate (1) the fitness of the issues for judicial decision and (2) the hardship to the parties of withholding court consideration.” *Nat’l Park Hosp. Ass’n. v. Dep’t of Interior*, 538 U.S. 803, 807-08 (2003) (ripeness doctrine “protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way”).

The preamble statements are not fit for judicial decision because EPA’s final risk evaluation of any given chemical will be highly fact-specific due to the variability

in different chemical substances and their uses. *See* EPA Response to Public Comment on Proposed Risk Evaluation Rule (ER 180-82). Until EPA compiles information about a chemical's conditions of use and excludes particular uses, it would be premature for this Court to consider the reasonableness of those decisions. *See Texas v. United States*, 523 U.S. 296, 300 (1998) (“A claim is not ripe . . . if it rests upon ‘contingent future events that may not occur as anticipated, or indeed may not occur at all.’”) (citation omitted). Additionally, the Court’s ultimate review should be informed by the “whole record” supporting such decisions—records that EPA will develop as it finalizes each risk evaluation. 5 U.S.C. § 706.

As an example, 1,4-dioxane is sometimes a byproduct from the reaction of other chemicals and consequently can be a contaminant in industrial, commercial, and consumer products. Technically, therefore, the byproduct 1,4-dioxane is a condition of use for both 1,4-dioxane and the other chemicals that contain it as a byproduct. Rather than including 1,4-dioxane as an impurity in the 1,4-dioxane risk evaluation, the preamble suggests that EPA may decide instead to include that condition of use in the risk evaluation for the reacted chemicals. Until EPA finalizes a decision on which risk evaluation an impurity belongs in and documents its decision in an administrative record, the issue is not fit for judicial decision.

Moreover, Petitioners will not suffer hardship if this Court withholds review of the hypothetical future exclusion of conditions of use because they will have ample opportunity to comment on the scope of individual risk evaluations and to seek

judicial review of any exclusion decisions. 40 C.F.R. §§ 702.41(c)(7) (draft scope documents subject to public comment), 702.49(a) (draft risk evaluations subject to public comment); 15 U.S.C. §§ 2605(i)(1) (judicial review for determination of no unreasonable risk), 2605(i)(2) (judicial review for risk management decision, which incorporates determination of unreasonable risk).

3. *Petitioners Lack Standing to Challenge the Preamble Statements.*

Third, Petitioners lack standing to challenge these statements for similar reasons. *See Bova v. City of Medford*, 564 F.3d 1093, 1095-96 (9th Cir. 2009) (noting ripeness and the injury prong of standing are interrelated). The “first and foremost” of the three standing elements is an “injury in fact” that is “concrete and particularized” and “actual or imminent, not conjectural or hypothetical.” *Spokeo*, 136 S. Ct. at 1547-48 (alterations and citations omitted). The remaining two elements, which often overlap, require that the injury be “fairly traceable to the challenged conduct of the defendant, and . . . likely to be redressed by a favorable judicial decision.” *Id.* at 1547. Petitioners cannot satisfy any of these elements.<sup>9</sup>

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<sup>9</sup> Petitioners rely on the three-part test for organizational standing in *Hunt v. Washington State Apple Advertising Commission*. Pet’rs Br. at 62. EPA does not dispute the second and third prongs of the *Hunt* test—that the interests Petitioners seek to protect are germane to their purpose and that individual members need not participate in these petitions for review. 432 U.S. 333, 343 (1977). However, Petitioners have failed to meet the first prong—that their members would have standing to sue in their own right. *Id.*

Petitioners' claimed injury is that their members "experience a credible threat of health harms from ongoing exposure to chemicals that EPA is currently evaluating pursuant to the Risk Evaluation Rule, including asbestos, 1,4-dioxane, PERC, TCE, and HBCD." Pet'rs Br. at 63. As an initial matter, EPA generally intends to follow the Risk Evaluation Rule with respect to those five chemicals (and the remaining five current risk evaluations) to the extent practicable. 82 Fed. Reg. at 33,726 (ER 1). But EPA is not bound to do so because EPA began these risk evaluations *before* promulgating the Risk Evaluation Rule. 40 C.F.R. § 702.35(a). Any alleged injury from EPA's review of these chemicals thus cannot be attributed to the Risk Evaluation Rule or its preamble.

Regardless, the mere "threat" of harm from these or other chemical substances that may undergo risk evaluation is too speculative to qualify as concrete, particularized, actual, or imminent under *Spokeo*. It could not be traceable to the preamble's equivocal and conditional statements. Such claims of injury really stem from the chemicals themselves, scoping decisions that EPA may make *in future actions*, and the eventual risk evaluation and risk management decision. *See La. Env'tl. Action Network v. Browner*, 87 F.3d 1379, 1383-84 (D.C. Cir. 1996) (no standing where claimed injury depends on discretionary action agency may take in the future). Using EPA's example of a de minimis use in a closed system that precludes exposure, 82 Fed. Reg. at 33,729 (ER 4), Petitioners' members are not likely to suffer an injury by exclusion of a condition of use that presents no exposure pathway. Or, suppose EPA excludes

from a risk evaluation the manufacture of a chemical as an impurity when it appears in a second substance because EPA has already assessed the impurity in the risk evaluation for the second substance. *See* 82 Fed. Reg. at 33,730 (ER 5). Petitioners are not likely to be injured by exclusion of a use already evaluated. The outcome of these future steps is highly fact-specific. It would be premature to assume now how EPA will act in the future.

Petitioners' own example proves the speculative nature and non-traceability of their alleged injury. Their brief points to the extra-record document stating EPA's expectation that it would not consider 1,4-dioxane as an impurity in other substances. Pet'rs Br. at 63-64. But this is a *non-final* document on which Petitioners were invited to comment, and nothing in the preamble dictates whether EPA will evaluate 1,4-dioxane impurities in the 1,4-dioxane risk evaluation or a separate risk evaluation, as noted above. Even assuming EPA ultimately applies the preamble discussion to the final risk evaluation for 1,4-dioxane, Petitioners are not imminently injured by the *potential* exclusion of 1,4-dioxane impurities from the scope of the 1,4-dioxane risk evaluation that EPA may capture in other risk evaluations.

Moreover, a ruling "vacating" EPA's preamble statements or even requiring EPA to include all conditions of use in each risk evaluation would not eliminate the alleged threat of harm from exposure to chemical substances. Including a condition of use in the scope of a risk evaluation does not guarantee that EPA will necessarily find an unreasonable risk for that use or any others. And there is nothing in the

regulation to vacate either. Eliminating the requirement in 40 C.F.R. § 702.41(c)(1) for scope documents to include “the condition(s) of use, as determined by the Administrator, that the EPA plans to consider in the risk evaluation” would only eliminate a regulation specifying the process Congress mandated.

Finally, Petitioners argue that because their members suffered “procedural injuries” by EPA’s promulgation of the Risk Evaluation Rule, they are entitled to a “relaxed” standard under *Cottonwood Environmental Law Center v. U.S. Forest Service*, 789 F.3d 1075, 1083 (9th Cir. 2015). Pet’rs Br. at 66. This argument is misplaced because the only harm Petitioners allege as traceable to the Rule is an increased risk of exposure to chemical substances, *id.* at 63-64. That is not a “procedural injury” akin to the claim in *Cottonwood* that an agency failed to follow a statutory mandate to consult with another agency. 789 F.3d at 1083. If anything, Petitioners have a higher standing bar here because they are not subject to the Rule or its preamble language. *See Lujan v. Defenders of Wildlife*, 504 U.S. 555, 561-62 (1992) (“[W]hen the plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily ‘substantially more difficult’ to establish.”) (citation omitted).

**C. Even if This Court Were to Review EPA’s Preamble Discussion, It Is Consistent with the Text and Purpose of the Act.**

Even if this Court reaches EPA’s preamble language, however, EPA’s discussion should be upheld. It is consistent with the statutory text, structure, and

purpose. Moreover, Petitioners' assertions of an unchecked process for excluding conditions of use on a whim are overblown in light of the statutory scheme, frequent opportunities for public comment, and availability of judicial review.

1. *The Statutory Text Confers Discretion.*

TSCA grants EPA discretion over the scope of risk evaluations. Section 6(b)(4)(D), 15 U.S.C. § 2605(b)(4)(D), requires that, as a first step in a risk evaluation, EPA must issue a document outlining the scope of the evaluation. In it, EPA must identify “the conditions of use . . . the [Agency] *expects to consider*” in a risk evaluation. *Id.* (emphasis added). If EPA must identify the conditions of use that EPA “expects to consider”—presumably among the universe of conditions of use it *could* consider—then EPA is not expected to necessarily consider *all* conditions of use and has discretion to decide what to include.

If Congress had intended EPA to include all activities that constitute conditions of use, Congress could have done so simply by saying that the scope document must include “*all* conditions of use” for a particular chemical or even “the circumstance the Administrator determined to constitute conditions of use.” Or Congress could have instructed EPA to identify the manufacture, processing, distribution in commerce, use and disposal that EPA has determined constitute conditions of use. It did not.

The Act includes other indications of discretionary scoping. Under section 18, 15 U.S.C. § 2617, state regulations are preempted where EPA has acted. But the

scope of preemption for risk evaluations only extends to “hazards, exposures, risks, and uses or conditions of use” included in a final risk evaluation or risk management rule. *Id.* § 2617(c)(3). If preemption only applies to conditions of use that *have* been included in an evaluation, then it must be possible for some conditions of use to have been excluded.

Petitioners argue that TSCA requires EPA to conduct risk evaluations on “a chemical substance” as a whole. *See* Pet’rs Br. at 24. Under the Rules, EPA will, in fact, issue final risk evaluations for entire chemical substances. *See* Fed. Reg. at 33,729 (ER 4). However, TSCA does not expressly require risk evaluation to be based on every circumstance conceivably associated with a chemical. It says only that the scope document must specify the conditions of use EPA expects to consider and that EPA must then determine whether the chemical presents an unreasonable risk under those conditions of use. 15 U.S.C. § 2605(b)(4)(A), (D). Under EPA’s discussed approach, that determination would focus on activities most likely to present an unreasonable risk.

Petitioners theorize that, in the context of section 6(b)(4)(A), “the” conditions of use means “all” conditions of use. Pet’rs Br. at 25. But this does not grapple with the discretion-granting language in section 6(b)(4)(D). 15 U.S.C. § 2605(b)(4)(D). Petitioners’ theory would render “expects to consider” superfluous. And the argument is inconsistent with common parlance. A law clerk instructed to review “the cases on final agency action” does not necessarily have to read each and every

case touching on the doctrine but merely enough cases to be able to make the required assessment.

Petitioners argue that, rather than conferring discretion, section 6(b)(4) withholds it because Congress did not use the word “discretion.” Pet’rs Br. at 27-28. That is not correct. Caselaw is rife with examples of phrases that confer discretion without using that specific word. *See, e.g., See Nat. Resources Def. Council*, 526 F.3d at 595 n.4 (phrase “as determined by the Administrator” confers discretion on EPA); *Nat’l Ass’n of Clean Air Agencies*, 489 F.3d at 1229 (phrase “as appropriate” confers “extraordinarily broad” discretion). And this very statute includes numerous phrases that unambiguously confer discretion without using the word. One example is section 6(b)(4)(F)(ii), which states that “[i]n conducting a risk evaluation under this subsection, the Administrator shall . . . describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered.” 15 U.S.C. § 2605(b)(4)(F)(ii). There, Congress did not mandate the use of either assessment mechanism but conferred discretion by requiring EPA to explain whether either was selected. Or, consider section 4(a)(1)(B)—“the Administrator shall . . . in the case of a chemical substance or mixture described in subparagraph (A)(i), by rule, order, or consent agreement, require that testing be conducted.” *Id.* § 2603(a)(1)(B). There, Congress gave EPA discretion to choose among listed alternatives. Likewise, here, Congress conferred discretion through requiring a risk evaluation scope document that includes “the conditions of use . . . the [Agency] expects to consider,”

necessarily implying that EPA may not “expect to consider” all conditions of use. *Id.* § 2605(b)(4)(D).

2. *EPA’s Discussed Approach Is Consistent with the Statutory Purpose and Legislative History.*

Moreover, EPA’s suggested approach is consistent with the Act’s purpose and legislative history. A critical, ultimate goal of section 6 is to regulate *unreasonable* risks, not to assess risks in the abstract. While EPA did not definitely or categorically exclude any circumstance that fits EPA’s interpretation of condition of use in this Rule, EPA contemplated exclusion only of activities EPA would not generally expect to present an unreasonable risk. 82 Fed. Reg. at 33,729 (ER 4). If EPA has reason to believe, before expending extensive resources that a use is not likely to pose an unreasonable risk because, say, it is in a closed system that does not present exposure pathways, it makes practical sense for EPA to exclude such a use, particularly in light of the tight statutory deadlines. *See id.* Or if EPA has information showing that another agency has already evaluated and regulated a condition of use such that unreasonable risk is not likely, it would be consistent with Congress’ triage scheme for EPA to focus on the unregulated and still potentially risky uses.

EPA reasonably suggested that a more flexible approach might better balance competing statutory mandates. These include the requirements for the continuous risk evaluations of at least 20 chemicals beginning soon, 15 U.S.C. § 2605(b)(2)(B),

(3)(C); detailed, technical analyses of risk on multiple chemicals and conditions of use at once, *id.* § 2605(b)(4)(F); and very tight statutory timeframes, *id.* § 2605(b)(4)(G).

Despite these obvious advantages, Petitioners argue that only an approach involving a “comprehensive[]” risk evaluation of all conditions of use would serve the Act’s goals. Pet’rs Br. at 30-33. Petitioners are wrong. Petitioners disregard the triage process Congress created to home in quickly on chemicals that may pose the most risk, *see infra* Argument I. Moreover, TSCA does not require an evaluation of all conditions of use, much less an aggregate assessment, as explained in the following section. *See infra* Argument IV.B. TSCA requires only an evaluation of the conditions of use included in the risk evaluation.

Additionally, contemporaneous statements by Senator Vitter, a primary author of the Lautenberg Act, expressly explain that EPA “is given the discretion to determine the conditions of use that the Agency will address in its evaluations of the priority chemicals” to ensure that EPA can control priority chemicals and meet statutory deadlines. 162 Cong. Rec. at S3519 col. 3. Petitioners’ only response to this statement is to say that four floor statements contradict it. But it is unclear which statements they mean as they simply cite to two pages of legislative history. Pet’rs Br. at 35 (citing 162 Cong. Rec. at S3518-19). Petitioners likely refer to language on S3519. 162 Cong. Rec. at S3519. This observes that risk assessments initiated before the Lautenberg Act were not conducted to address all conditions of use and that EPA recommended adding section 26(j)(4), later codified at 15 U.S.C. § 2625(j)(4), to avoid

the need “to reexamine and perhaps broaden” the scopes of previous risk assessments. *Id.* This language supports EPA’s preamble discussion. Section 26(j)(4) exempts previously-completed risk assessments from the section 6 risk evaluation process and allows EPA to skip directly to the risk management phase for the conditions of use included in the assessment, 15 U.S.C. § 2625(j)(4). This section merely suggests that Congress did not intend for the new process to impede progress from prior risk assessments. Nothing in the cited statements means that Congress expected EPA to include all conditions of use in *new* risk evaluations. But Senator Boxer’s statement that section 26(j)(4) would avoid the need to “reexamine and *perhaps* broaden” the scope of prior risk evaluations at least hints at potential circumstances in which fewer than all of the conditions of use had been assessed but where it would not be necessary to broaden the scope, even without section 26(j)(4). *See id.* § 2625(j)(4) (emphasis added).

Finally, Petitioners’ approach could lead to absurd results because some activities could constitute a condition of use for more than one chemical. Returning to the 1,4-dioxane example, *see supra* Argument II.B.2, that chemical is manufactured as both a commodity chemical and as a byproduct from the reaction of other chemicals. If EPA has already evaluated the use under one risk evaluation, should EPA be required to consider it *again*? Such a cumbersome result would not be consistent with Congress’ triage scheme or the efficient use of limited agency resources under tight statutory deadlines. At a minimum, EPA should have some

discretion to determine what is appropriate and consistent with the Act under such highly fact-specific and technical circumstances.

3. *In Any Case, Petitioners' Allegations of "Unfettered Discretion" Are Overblown Because Each Scoping Decision Is Independently Reasonable and Must Be Consistent with the Act.*

Petitioners' characterization of EPA's discussion as "pick and choose," giving EPA "unlimited discretion" to exclude any activity it wants, Pet'rs Br. at 21, 22, 26, is inflated.

Under EPA's discussed approach, EPA would make a "fact specific," "case-by-case" determination. 82 Fed. Reg. at 33,730 (ER 5). "The Agency is committed to exercising its discretion to determine the conditions of use in a reasonable manner and will not base this determination upon hypotheticals or conjecture." *Id.* This is a reasonable approach because some decisions that might make sense on a case-by-case basis may not be universally reasonable. And each individual scoping decision would have to be independently consistent with the statutory scheme and congressional intent. If EPA were to, for example, exclude a use with no explanation of why the exclusion is consistent with TSCA, it would likely be invalid on its face and would not withstand judicial review. *See* 15 U.S.C. §§ 2605(i)(1)-(2), 2618(a)(1)(A).

Additionally, hypothetical exclusion of a condition of use in one circumstance would not necessarily mean that an activity is never assessed or regulated. For example, it may be appropriate to evaluate a chemical byproduct that appears in more than one substance along with one of the substances in which it appears, rather than

with the remaining uses for that byproduct. 82 Fed. Reg. at 33,730 (ER 5). EPA's decision to exclude the byproduct as a condition of use in one circumstance does not mean it will not evaluate that same byproduct elsewhere. And any excluded condition of use could still be regulated by states because the TSCA preemption clause does not apply to activities that EPA excludes. 15 U.S.C § 2617(c)(2), (3) (federal preemption applies only to conditions of use included in scope of risk evaluation or in risk management regulation).

EPA's discussion was about improving its ability "to focus on conducting a timely, relevant, high-quality, and scientifically credible evaluation of a chemical substance" and to "always include[] an evaluation of the conditions of use that raise greatest potential for risk." 82 Fed. Reg. at 33,728 (ER 3). This is appropriate and consistent with the Act, and Petitioners' claim should be denied.

### **III. The Risk Evaluation Rule's Provision on Iterative Risk Evaluations Is Consistent with TSCA.**

Under the Risk Evaluation Rule, when EPA has sufficient information to determine that a chemical either does or does not present an unreasonable risk under a particular condition of use, EPA may publish an early risk evaluation document (i.e., an early risk determination) for that particular condition of use while review of the remaining conditions of use is still in progress. 40 C.F.R. § 702.47; 82 Fed. Reg. at 33,729 (ER 4). Petitioners claim EPA may only issue early risk determinations for particular conditions of use when it finds an unreasonable risk, but not when it finds

no unreasonable risk. Pet'rs Br. Arg. II, at 39-40. This is contradictory and evidences a fundamental misunderstanding of the requirements of TSCA and of the Rule.

EPA's iterative approach to risk determinations is both permissible and consistent with Congress' triage scheme. It will help EPA focus its limited resources on the circumstances potentially posing the most risks.

**A. Petitioners Do Not Dispute that EPA Has Authority to Issue Early Risk Evaluations.**

The Act says only that EPA must evaluate “the chemical substance . . . under the conditions of use” and that EPA must normally complete the risk evaluation within three years. 15 U.S.C. § 2605(b)(4)(A), (G)(i). It does not say that EPA must do this all at once. Statutory silence on this point gives EPA discretion to evaluate a substance's conditions of use one at a time or in groups if there is a reasonable basis to do so.<sup>10</sup> *See, e.g., Entergy Corp.*, 556 U.S. at 222-23 (statutory silence demonstrates delegation of discretion).

Petitioners do not dispute that EPA has authority to conduct iterative risk evaluations. They expressly acknowledge that early risk determinations are permissible where EPA concludes that a condition of use *does* pose an unreasonable risk. Pet'rs Br. at 40. Rather, Petitioners paradoxically argue that TSCA requires EPA to conduct a holistic analysis of all condition of use at once but that this alleged

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<sup>10</sup> *See also* 162 Cong. Rec. at S3521 col. 2 (“[T]hese determinations are made on a use-by-use basis.”).

holistic requirement only extends to conditions of use that EPA has determined *do not* pose an unreasonable risk. Pet’rs Br. at 39-40. No statutory basis supports this interpretation.

**B. TSCA Does Not Require Aggregate Risk Assessments, and Nothing in the Risk Evaluation Rule Prevents Them Where Warranted.**

Petitioners essentially make a policy argument camouflaged as a legal one—they contend that TSCA requires EPA to conduct a “holistic” risk evaluation. Pet’rs Br. at 39. In other words, Petitioners argue that for every chemical EPA evaluates, it must determine whether the chemical poses an unreasonable risk *in the aggregate* before determining whether any one condition of use does not present an unreasonable risk. *Id.* 39-40. The Act does not support this contention.

TSCA expressly gives EPA discretion over whether or not to conduct aggregate risk exposure assessments for each chemical evaluated. Section 6(b)(4)(F), which lists the statutory requirements for risk evaluations, states that each risk evaluation must “describe *whether* aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration.” 15 U.S.C. § 2605(b)(4)(F)(ii) (emphasis added). Nothing says EPA *must* use an aggregate model in each risk evaluation. Even where EPA does choose an aggregate approach, TSCA does not require EPA to always include every condition of use in the model. For example, EPA may not believe it is appropriate to include in an aggregation a particular condition of use that presents either no risk or a risk concern

(e.g., dermal exposure) that is not raised by other conditions of use (e.g., risks from inhalation). Where EPA does not believe it makes sense to do so, EPA is free to not aggregate risks.

TSCA is very different in this way from other statutes that do require aggregate assessments. For example, the Federal Food, Drug, and Cosmetic Act requires EPA to set maximum levels for pesticides in food. 21 U.S.C. § 346a(b)(2)(A)(i). In doing so, EPA must determine the level is “safe,” defined as “no harm will result from an aggregate exposure to the pesticide chemical residue.” *Id.* § 346a(b)(2)(A)(ii); *see also id.* § 346a(b)(2)(D)(vi) (EPA shall consider “available information concerning the aggregate exposure levels of consumers . . . to the pesticide chemical residue”). TSCA has no similar language.

Petitioners argue that EPA’s rule is facially invalid because, they claim, EPA might determine that a chemical poses no risk under multiple minor uses when it might pose a risk in totality. Pet’rs Br. at 39. While EPA does not deny the possibility of this circumstance for a particular chemical, an equally or more likely scenario for a particular chemical is that exposure may truly present no unreasonable risk under one condition of use (e.g., a circumstance where inhalation is unlikely or impossible) but pose unreasonable risks under another (e.g., a circumstance where inhalation is prevalent). Another possible example is a chemical that presents 98 percent of all exposure from just two conditions of use, while the remaining 2 percent of exposure comes from ten additional uses.

Importantly, EPA's approach reasonably addresses *all* of these possibilities. If a chemical has many conditions of use presenting many small exposures that are appropriate to aggregate under section 6(b)(4)(F)(ii), EPA may choose the aggregate exposure approach and issue one risk determination document for all conditions of use. 15 U.S.C. § 2605(b)(4)(F)(ii). Nothing in the Rule prevents EPA from doing so. *See* 40 C.F.R. § 702.47 (stating only that EPA will determine whether there is an unreasonable risk in one or multiple documents). Indeed, EPA expressly explained that any such decisions would "be highly fact-specific" and that EPA is committed to making decisions in a reasonable manner. 82 Fed. Reg. at 33,730 (ER 5). But if EPA can determine that a particular condition of use presents no unreasonable risk, EPA could reasonably issue an early risk determination for that condition of use. 40 C.F.R. § 702.47.

The Court need not address such hypotheticals here. Every risk evaluation by EPA, including early risk determinations and decisions to rely on a sentinel rather than an aggregate exposure approach, is subject to public comment and is judicially reviewable. 15 U.S.C. §§ 2605(i)(1)-(2), 2618(a)(1)(A); *see also* 82 Fed. Reg. at 33,740 (ER 15). The Court should not handicap EPA's ability to issue early risk determinations in case-appropriate circumstances simply because it may not be appropriate in all circumstances.

#### **IV. The Information-Gathering and Consideration Provisions Still at Issue Should Be Upheld.**

Petitioners also challenge a series of provisions in the Rules concerning how EPA collects and considers information. Pet'rs Br. Arg. IV, at 51-61. For the reasons explained in its Motion for Voluntary Remand filed separately, EPA seeks voluntary remand of three of those provisions, 40 C.F.R. §§ 702.31(d) and 702.37(b)(4) and (b)(6), discussed in sections IV.A, IV.B, and IV.C of Petitioners' brief. The remaining challenged provisions, 40 C.F.R. §§ 702.5(e) and 702.9(b), are reasonable and should be upheld.

##### **A. TSCA Requires EPA to Consider Information Consistent with Scientific Standards.**

The Prioritization Rule states that, during EPA's initial screen of chemical substances, "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)." 40 C.F.R. § 702.9(b). Petitioners claim that this provision unlawfully "erect[s] a 'screen' that excludes some reasonably available information from EPA's prioritization process—rather than allowing EPA to weigh that information." Pet'rs Br. at 58.

Petitioners' argument is plainly contradicted by the text of the regulation, which simply reiterates EPA's compliance with section 26(h) of TSCA. Section 26(h) states that, when EPA makes decisions based on science, the Agency "shall use scientific information, technical procedures, measures, methods, protocols, methodologies, or

models, employed in a manner consistent with the best available science, and shall consider as applicable” five factors, such as whether the information “is relevant for [EPA’s] use” or has been peer reviewed. 15 U.S.C. § 2625(h). EPA had not expressly incorporated section 26(h) or certain other TSCA requirements into the proposed rule, because “these statutory requirements apply to EPA’s decisions under TSCA section 6, without the need for regulatory action.” Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act, Proposed Rule, 82 Fed. Reg. 4827-28 (Jan. 17, 2017) (ER 579-80). But in response to public comments urging EPA to address the role of section 26(h), EPA did so in the final Rule. 82 Fed. Reg. at 33,756-57 (ER 32-33).

Petitioners argue that a different TSCA provision, which states that EPA “shall take into consideration information . . . that is reasonably available to the Administrator,” *id.* § 2625(k), governs. Pet’rs Br. at 51-52. But EPA must comply with *both* sections 2625(h) and (k). And the Rule does incorporate both statutory provisions. Section 702.9(b) addresses section 2625(h), while section 702.9(a) addresses section 2625(k) by stating that “EPA will generally use reasonably available information to screen the candidate chemical substance,” 40 C.F.R. § 702.9(a). Regardless, there is no inconsistency between these two provisions, and section 702.9(b) does not screen out information but rather explains how EPA will assess the quality of information. Under Petitioners’ interpretation, section 26(h) would be rendered surplusage.

Section 702.9(b) should be upheld.

**B. EPA Can Acquire Information Necessary to Complete Risk Evaluations.**

Section 702.5(e) in the Prioritization Rule states: “if EPA believes it would not have sufficient information for purposes of prioritization, EPA generally expects to obtain [the necessary information] prior to initiating the process.” 40 C.F.R.

§ 702.5(e). Petitioners contend this provision is too narrow and will result in EPA initiating risk evaluations without sufficient information. Pet’rs Br. at 60-61.

Petitioners misunderstand the provision.

Section 702.5(e) is the complement of section 702.7(a). Yet Petitioners do not make any arguments about the latter section. Section 702.7(a) states that EPA intends to initiate the prioritization process “only when it believes that the information necessary to prioritize the substance is reasonably available.” 40 C.F.R. § 702.7(a).

Together, these state that the amount of information necessary to complete prioritization is the *minimum* amount EPA will generally require to initiate prioritization. Neither precludes EPA from compiling sufficient information to conduct both prioritization and risk evaluation for a chemical substance. They provide a floor, not a ceiling.

As explained in the preamble, “EPA expects to consider the existence and availability of risk-related information on a candidate chemical substance before initiating the prioritization process.” 82 Fed. Reg. at 33,758 (ER 34). This includes all

risk-related information. In fact, the hazard and exposure information needed for prioritization is also needed to conduct risk evaluations. Moreover, these provisions relate only to the *initiation* of prioritization. During prioritization, EPA can obtain further risk-related information through, for example, two 90-day comment periods. *Id.* at 33,757-78 (ER 33-34). Where appropriate, EPA also has authorities to require submission or generation of new data. *Id.* To the extent a party is concerned that EPA does not have sufficient information at the prioritization stage to complete a risk evaluation, the party can raise the issue during public comment. 40 C.F.R. §§ 702.7(d), 702.9(g).

Finally, this provision is part of the Prioritization Rule, which sets forth EPA's procedures to conduct *prioritizations*. The Risk Evaluation Rule contains separate procedures for EPA to obtain the information necessary to conduct risk evaluations. *Id.* § 702.41(b)(2), (b)(5). Section 702.5(e) should be upheld.

**V. Petitioners' Request for Vacatur Is Unsupported and Includes Provisions Never Discussed in Petitioners' Brief.**

Setting aside Petitioners' erroneous legal arguments, Petitioners also ask this Court to vacate many provisions in the Rules and their preambles without arguing why these provisions are invalid or should be vacated. *See* Pet'rs Br. at 70.

Petitioners make *no* argument regarding the following provisions and preambular sections until the final page of their brief summarily requesting vacatur and remand:

- 40 C.F.R. § 702.7(a) (EPA will only initiate prioritizations if it has enough information to complete prioritization);
- 40 C.F.R. § 702.9(c) (EPA will propose to designate a chemical substance as high- or low-priority based in part on “other information as appropriate and consistent with 15 U.S.C. 2625(h) and (i));
- 40 C.F.R. § 702.37, excluding (e)(3) and (b)(3) (setting forth process for manufacturer requests for risk evaluations);
- 40 C.F.R. § 702.41(a)(7) (EPA may determine it requires no further information to evaluate a particular condition of use);
- 40 C.F.R. § 702.41(b)(2) (EPA will initiate a risk evaluation when it believes it has all or most of the information necessary to perform a risk evaluation and will use its TSCA authority to acquire other information);
- 40 C.F.R. § 702.43(a)(1) (risk characterizations will integrate hazard and exposure assessments into qualitative and/or quantitative estimates for identified populations);
- Prioritization Rule preamble IV.J (ER 34), 82 Fed. Reg. at 33,758 (discussion of “Information Availability”);
- Risk Evaluation Rule preamble III.G (ER 10-13), 82 Fed. Reg. at 33,735-38 (Section entitled “Process and Criteria for Manufacturer Requested Risk Evaluations”);

- Risk Evaluation Rule preamble III.H.d (ER 14), 82 Fed. Reg. at 33,739 (under “fit-for-purpose” risk evaluations, evaluation will vary based on characteristics of a particular chemical).

Pet’rs Br. at 70. Petitioners have waived any argument about these provisions and preamble language and are precluded from providing a new rationale in their reply brief. *See Kama*, 394 F.3d at 1238 (“Generally, an issue is waived when the appellant does not specifically and distinctly argue the issue in his or her opening brief.”).

A handful of other provisions and preambular statements appear loosely relevant to Petitioners’ substantive claims, yet they include extensive portions that are not the subject of Petitioners’ claims:

- 40 C.F.R. § 702.41(a)(5), (a)(8), (a)(9), (c)(4)(i), (c)(4)(iii), (d)(2) (specifying considerations and components of scope documents such as requiring that the scope be well-tailored and include conceptual models);
- 40 C.F.R. § 702.49(b), (c), (d) (setting timeframes for completing risk evaluations);
- Prioritization Rule preamble IV.B (ER 31), 82 Fed. Reg. at 33,755 (discussion of risk evaluation scope, including matters not related to Petitioners’ claims, such as that prioritizations will be based on a whole chemical, not individual conditions of use);

- Risk Evaluation Rule preamble III.I.1 (ER 16), 82 Fed. Reg. at 33,741 (section on scope documents discussing many components never mentioned in Petitioners’ brief, including hazards, susceptible subpopulations, and conceptual models); and
- Risk Evaluation Rule preamble III.I.6 (ER 19), 82 Fed. Reg. at 33,744 (section entitled “Unreasonable risk determination” discussing several issues such as that risk evaluations will include a finding for each included condition of use).

Pet’rs Br. at 70. Petitioners raise no argument as to the invalidity of these provisions other than to note that they refer in some fashion to “the conditions of use within the scope of the evaluation.” *Id.* at 22. They have therefore waived any argument that they should be vacated in their entirety.

Petitioners state in passing that sections 702.37(e)(3) and (b)(3) allow EPA to limit risk evaluations requested by manufacturers to the conditions of use identified by manufacturers, but make no argument to support this false assertion or explain why this would render the provisions invalid. Pet’rs Br. at 22. In fact, 40 C.F.R. § 702.37(e)(3) states that EPA will “assess what, if any, additional conditions of use . . . warrant inclusion within the scope” of a manufacturer-requested risk evaluation and that this will be “based on the same considerations” as chemicals already deemed high-priority.

Finally, Petitioners do not adequately make a case for vacatur as to any provision. “Whether agency action should be vacated depends on how serious the agency’s errors are ‘and the disruptive consequences of an interim change that may itself be changed.’” *Cal. Cmty. Against Toxics v. EPA*, 688 F.3d 989, 992 (9th Cir. 2012) (citation omitted). With the exception of a few provisions for which EPA is voluntarily seeking remand, the challenged portions of the Rules are reasonable and supported by the administrative records. Because these are foundational rules that guide EPA’s process of implementing the TSCA amendments, vacatur could be disruptive to EPA’s ongoing statutory obligations. It is difficult to address the nature of any potential error and the consequences of vacatur in the absence of the Court’s opinion. Thus, if the Court finds an error with any of the provisions challenged by Petitioners, EPA requests that the parties be permitted to submit supplemental briefs on remedy after the Court renders its opinion.

## **CONCLUSION**

For these reasons, these Petitions should be denied.

Respectfully submitted,

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AUGUST 6, 2018

## **STATEMENT OF RELATED CASES**

Pursuant to Ninth Circuit Rule 28-2.6, EPA states that it is not aware of any related cases other than those that have been consolidated here.

**CERTIFICATE OF COMPLIANCE WITH  
FEDERAL RULE OF APPELLATE PROCEDURE 32(A)**

I hereby certify that this brief complies with the requirements of Fed. R. App. P. 32(a)(5) and (6) because it has been prepared in 14-point Garamond, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Circuit Rules 32-1(a) and 32-2(b) because it contains 15,356 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), as counted by Microsoft Word.

s/Samara M. Spence  
SAMARA M. SPENCE

**CERTIFICATE OF SERVICE**

I hereby certify that I electronically filed the above brief with the Clerk of the Court through the Court's CM/ECF system on August 6, 2018, which will serve all counsel of record in this case.

*s/ Samara M. Spence*  
\_\_\_\_\_  
SAMARA M. SPENCE

## **STATUTORY AND REGULATORY ADDENDUM**

**STATUTORY AND REGULATORY ADDENDUM**

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Except for the following, all applicable Statutes and Code of Federal Regulations, are contained in Petitioners' Addendum.

**Statutes**

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15 U.S.C. § 2603 .....	ADD02
15 U.S.C. § 2604 .....	ADD09
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40 C.F.R. § 702.47 .....	ADD41
40 C.F.R. § 702.49 .....	ADD41

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface to the report.

## AMENDMENTS

1976—Pub. L. 94-574 provided that if no special statutory review proceeding is applicable, the action for judicial review may be brought against the United States, the agency by its official title, or the appropriate officer as defendant.

**§ 704. Actions reviewable**

Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. A preliminary, procedural, or intermediate agency action or ruling not directly reviewable is subject to review on the review of the final agency action. Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 392.)

## HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
.....	5 U.S.C. 1009(c).	June 11, 1946, ch. 324, §10(c), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

**§ 705. Relief pending review**

When an agency finds that justice so requires, it may postpone the effective date of action taken by it, pending judicial review. On such conditions as may be required and to the extent necessary to prevent irreparable injury, the reviewing court, including the court to which a case may be taken on appeal from or on application for certiorari or other writ to a reviewing court, may issue all necessary and appropriate process to postpone the effective date of an agency action or to preserve status or rights pending conclusion of the review proceedings.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

## HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
.....	5 U.S.C. 1009(d).	June 11, 1946, ch. 324, §10(d), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

**§ 706. Scope of review**

To the extent necessary to decision and when presented, the reviewing court shall decide all relevant questions of law, interpret constitutional and statutory provisions, and determine the meaning or applicability of the terms of an agency action. The reviewing court shall—

(1) compel agency action unlawfully withheld or unreasonably delayed; and

(2) hold unlawful and set aside agency action, findings, and conclusions found to be—

(A) arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law;

(B) contrary to constitutional right, power, privilege, or immunity;

(C) in excess of statutory jurisdiction, authority, or limitations, or short of statutory right;

(D) without observance of procedure required by law;

(E) unsupported by substantial evidence in a case subject to sections 556 and 557 of this title or otherwise reviewed on the record of an agency hearing provided by statute; or

(F) unwarranted by the facts to the extent that the facts are subject to trial de novo by the reviewing court.

In making the foregoing determinations, the court shall review the whole record or those parts of it cited by a party, and due account shall be taken of the rule of prejudicial error.

(Pub. L. 89-554, Sept. 6, 1966, 80 Stat. 393.)

## HISTORICAL AND REVISION NOTES

Derivation	U.S. Code	Revised Statutes and Statutes at Large
.....	5 U.S.C. 1009(e).	June 11, 1946, ch. 324, §10(e), 60 Stat. 243.

Standard changes are made to conform with the definitions applicable and the style of this title as outlined in the preface of this report.

## ABBREVIATION OF RECORD

Pub. L. 85-791, Aug. 28, 1958, 72 Stat. 941, which authorized abbreviation of record on review or enforcement of orders of administrative agencies and review on the original papers, provided, in section 35 thereof, that: "This Act [see Tables for classification] shall not be construed to repeal or modify any provision of the Administrative Procedure Act [see Short Title note set out preceding section 551 of this title]."

**CHAPTER 8—CONGRESSIONAL REVIEW OF AGENCY RULEMAKING**

Sec. 801.	Congressional review.
802.	Congressional disapproval procedure.
803.	Special rule on statutory, regulatory, and judicial deadlines.
804.	Definitions.
805.	Judicial review.
806.	Applicability; severability.
807.	Exemption for monetary policy.
808.	Effective date of certain rules.

**§ 801. Congressional review**

(a)(1)(A) Before a rule can take effect, the Federal agency promulgating such rule shall submit to each House of the Congress and to the Comptroller General a report containing—

(i) a copy of the rule;

(ii) a concise general statement relating to the rule, including whether it is a major rule; and

(iii) the proposed effective date of the rule.

(B) On the date of the submission of the report under subparagraph (A), the Federal agency pro-

(A) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or

(B) as part of an article containing the chemical substance or mixture.

(14) The term "processor" means any person who processes a chemical substance or mixture.

(15) The term "protocols and methodologies for the development of information" means a prescription of—

(A) the—

- (i) health and environmental effects, and
- (ii) information relating to toxicity, persistence, and other characteristics which affect health and the environment,

for which information for a chemical substance or mixture are to be developed and any analysis that is to be performed on such information, and

(B) to the extent necessary to assure that information respecting such effects and characteristics are reliable and adequate—

- (i) the manner in which such information are<sup>2</sup> to be developed,
- (ii) the specification of any test protocol or methodology to be employed in the development of such information, and
- (iii) such other requirements as are necessary to provide such assurance.

(16) The term "State" means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

(17) The term "United States", when used in the geographic sense, means all of the States.

(Pub. L. 94-469, title I, §3, Oct. 11, 1976, 90 Stat. 2004; Pub. L. 99-514, §2, Oct. 22, 1986, 100 Stat. 2095; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub. L. 100-418, title I, §1214(e)(1), Aug. 23, 1988, 102 Stat. 1156; Pub. L. 114-92, div. A, title III, §315, Nov. 25, 2015, 129 Stat. 791; Pub. L. 114-182, title I, §§3, 19(c), June 22, 2016, 130 Stat. 448, 505.)

#### REFERENCES IN TEXT

The Federal Insecticide, Fungicide, and Rodenticide Act, referred to in par. (2)(B)(ii), is act June 25, 1947, ch. 125, as amended generally by Pub. L. 92-516, Oct. 21, 1972, 86 Stat. 973, which is classified generally to subchapter II (§136 et seq.) of chapter 6 of Title 7, Agriculture. For complete classification of this Act to the Code, see Short Title note set out under section 136 of Title 7 and Tables.

The Atomic Energy Act of 1954, referred to in par. (2)(B)(iv), is act Aug. 1, 1946, ch. 724, as added by act Aug. 30, 1954, ch. 1073, §1, 68 Stat. 919, and amended, which is classified principally to chapter 23 (§2011 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 2011 of Title 42 and Tables.

The Harmonized Tariff Schedule of the United States, referred to in par. (9), is not set out in the Code. See Publication of Harmonized Tariff Schedule note set out under section 1202 of Title 19, Customs Duties.

For definition of Canal Zone, Governor of the Canal Zone, and Panama Canal Company, referred to in par.

(16), see section 3602(b) of Title 22, Foreign Relations and Intercourse.

#### AMENDMENTS

2016—Pars. (4) to (7). Pub. L. 114-182, §3(1)–(3), added pars. (4) and (7) and redesignated former pars. (4) and (5) as (5) and (6), respectively. Former pars. (6) and (7) redesignated (8) and (9), respectively.

Par. (8). Pub. L. 114-182, §19(c)(1), substituted "information" for "data".

Pub. L. 114-182, §3(1), redesignated par. (6) as (8). Former par. (8) redesignated (10).

Pars. (9) to (14). Pub. L. 114-182, §3(1), (4), added par. (12) and redesignated former pars. (7) to (11) as (9), (10), (11), (13), and (14), respectively. Former pars. (12) to (14) redesignated (16) to (17), respectively.

Par. (15). Pub. L. 114-182, §19(c)(2)(A), (B), in introductory provisions, substituted "protocols and methodologies for the development of information" for "standards for the development of test data".

Pub. L. 114-182, §3(1), redesignated par. (12) as (15).

Par. (15)(A). Pub. L. 114-182, §19(c)(2)(C), substituted "on such information" for "on such data" in concluding provisions.

Pub. L. 114-182, §19(c)(2)(B), substituted "for which information" for "for which test data" in concluding provisions.

Par. (15)(B). Pub. L. 114-182, §19(c)(2)(C), substituted "information" for "data" wherever appearing.

Pars. (16), (17). Pub. L. 114-182, §3(1), redesignated pars. (13) and (14) as (16) and (17), respectively.

2015—Par. (2)(B)(v). Pub. L. 114-92 substituted "and any component of such an article (limited to shot shells, cartridges, and components of shot shells and cartridges), and" for "and".

1988—Par. (7). Pub. L. 100-418 substituted "general note 2 of the Harmonized Tariff Schedule of the United States" for "general headnote 2 of the Tariff Schedules of the United States".

1986—Par. (2)(B)(v). Pub. L. 99-514 substituted "Internal Revenue Code of 1986" for "Internal Revenue Code of 1954".

#### EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100-418 effective Jan. 1, 1989, and applicable with respect to articles entered on or after such date, see section 1217(b)(1) of Pub. L. 100-418, set out as an Effective Date note under section 3001 of Title 19, Customs Duties.

#### EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

#### § 2603. Testing of chemical substances and mixtures

##### (a) Testing requirements

(1) If the Administrator finds that—

(A)(i)(I) the manufacture, distribution in commerce, processing, use, or disposal of a chemical substance or mixture, or that any combination of such activities, may present an unreasonable risk of injury to health or the environment,

(II) there is insufficient information and experience upon which the effects of such manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(III) testing of such substance or mixture with respect to such effects is necessary to develop such information; or

(ii)(I) a chemical substance or mixture is or will be produced in substantial quantities, and

<sup>2</sup>So in original. Probably should be "is".

(aa) it enters or may reasonably be anticipated to enter the environment in substantial quantities or (bb) there is or may be significant or substantial human exposure to such substance or mixture,

(II) there is insufficient information and experience upon which the effects of the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture or of any combination of such activities on health or the environment can reasonably be determined or predicted, and

(III) testing of such substance or mixture with respect to such effects is necessary to develop such information; and

(B) in the case of a mixture, the effects which the mixture's manufacture, distribution in commerce, processing, use, or disposal or any combination of such activities may have on health or the environment may not be reasonably and more efficiently determined or predicted by testing the chemical substances which comprise the mixture;

the Administrator shall by rule, or, in the case of a chemical substance or mixture described in subparagraph (A)(i), by rule, order, or consent agreement, require that testing be conducted on such substance or mixture to develop information with respect to the health and environmental effects for which there is an insufficiency of information and experience and which is relevant to a determination that the manufacture, distribution in commerce, processing, use, or disposal of such substance or mixture, or that any combination of such activities, does or does not present an unreasonable risk of injury to health or the environment.

(2) **ADDITIONAL TESTING AUTHORITY.**—In addition to the authority provided under paragraph (1), the Administrator may, by rule, order, or consent agreement—

(A) require the development of new information relating to a chemical substance or mixture if the Administrator determines that the information is necessary—

(i) to review a notice under section 2604 of this title or to perform a risk evaluation under section 2605(b) of this title;

(ii) to implement a requirement imposed in a rule, order, or consent agreement under subsection (e) or (f) of section 2604 of this title or in a rule promulgated under section 2605(a) of this title;

(iii) at the request of a Federal implementing authority under another Federal law, to meet the regulatory testing needs of that authority with regard to toxicity and exposure; or

(iv) pursuant to section 2611(a)(2) of this title; and

(B) require the development of new information for the purposes of prioritizing a chemical substance under section 2605(b) of this title only if the Administrator determines that such information is necessary to establish the priority of the substance, subject to the limitations that—

(i) not later than 90 days after the date of receipt of information regarding a chemical substance complying with a rule, order, or

consent agreement under this subparagraph, the Administrator shall designate the chemical substance as a high-priority substance or a low-priority substance; and

(ii) information required by the Administrator under this subparagraph shall not be required for the purposes of establishing or implementing a minimum information requirement of broader applicability.

(3) **STATEMENT OF NEED.**—When requiring the development of new information relating to a chemical substance or mixture under paragraph (2), the Administrator shall identify the need for the new information, describe how information reasonably available to the Administrator was used to inform the decision to require new information, explain the basis for any decision that requires the use of vertebrate animals, and, as applicable, explain why issuance of an order is warranted instead of promulgating a rule or entering into a consent agreement.

(4) **TIERED TESTING.**—When requiring the development of new information under this subsection, the Administrator shall employ a tiered screening and testing process, under which the results of screening-level tests or assessments of available information inform the decision as to whether 1 or more additional tests are necessary, unless information available to the Administrator justifies more advanced testing of potential health or environmental effects or potential exposure without first conducting screening-level testing.

**(b) Testing requirement rule, order, or consent agreement**

(1) A rule, order, or consent agreement under subsection (a) shall include—

(A) identification of the chemical substance or mixture for which testing is required under the rule, order, or consent agreement,

(B) protocols and methodologies for the development of information for such substance or mixture, and

(C) with respect to chemical substances which are not new chemical substances and to mixtures, a specification of the period (which period may not be of unreasonable duration) within which the persons required to conduct the testing shall submit to the Administrator information developed in accordance with the protocols and methodologies referred to in subparagraph (B).

In determining the protocols and methodologies and period to be included, pursuant to subparagraphs (B) and (C), in a rule, order, or consent agreement under subsection (a), the Administrator's considerations shall include the relative costs of the various test protocols and methodologies which may be required under the rule, order, or consent agreement and the reasonably foreseeable availability of the facilities and personnel needed to perform the testing required under the rule, order, or consent agreement. Any such rule, order, or consent agreement may require the submission to the Administrator of preliminary information during the period prescribed under subparagraph (C).

(2)(A) The health and environmental effects for which protocols and methodologies for the

development of information may be prescribed include carcinogenesis, mutagenesis, teratogenesis, behavioral disorders, cumulative or synergistic effects, and any other effect which may present an unreasonable risk of injury to health or the environment. Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment. The characteristics of chemical substances and mixtures for which such protocols and methodologies may be prescribed include persistence, acute toxicity, subacute toxicity, chronic toxicity, and any other characteristic which may present such a risk. The methodologies that may be prescribed in such protocols and methodologies include epidemiologic studies, serial or tiered testing, in vitro tests, and whole animal tests, except that before prescribing epidemiologic studies of employees, the Administrator shall consult with the Director of the National Institute for Occupational Safety and Health.

(B) From time to time, but not less than once each 12 months, the Administrator shall review the adequacy of the protocols and methodologies for development of information prescribed in rules, orders, and consent agreements under subsection (a) and shall, if necessary, institute proceedings to make appropriate revisions of such protocols and methodologies.

(3)(A) A rule or order under subsection (a) respecting a chemical substance or mixture shall require the persons described in subparagraph (B) or (C), as applicable, to conduct tests and submit information to the Administrator on such substance or mixture, except that the Administrator may permit two or more of such persons to designate one such person or a qualified third party to conduct such tests and submit such information on behalf of the persons making the designation.

(B) The following persons shall be required to conduct tests and submit information on a chemical substance or mixture subject to a rule under subsection (a)(1):

(i) Each person who manufactures or intends to manufacture such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II) with respect to the manufacture of such substance or mixture.

(ii) Each person who processes or intends to process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II) with respect to the processing of such substance or mixture.

(iii) Each person who manufactures or processes or intends to manufacture or process such substance or mixture if the Administrator makes a finding described in subsection (a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II) with respect to the distribution in commerce, use, or disposal of such substance or mixture.

(C) A rule or order under paragraph (1) or (2) of subsection (a) may require the development of information by any person who manufactures or processes, or intends to manufacture or process, a chemical substance or mixture subject to the rule or order.

(4) Any rule, order, or consent agreement under subsection (a) requiring the testing of and submission of information for a particular chemical substance or mixture shall expire at the end of the reimbursement period (as defined in subsection (c)(3)(B)) which is applicable to information for such substance or mixture unless the Administrator repeals the rule or order or modifies the consent agreement to terminate the requirement before such date; and a rule, order, or consent agreement under subsection (a) requiring the testing of and submission of information for a category of chemical substances or mixtures shall expire with respect to a chemical substance or mixture included in the category at the end of the reimbursement period (as so defined) which is applicable to information for such substance or mixture unless the Administrator before such date repeals or modifies the application of the rule, order, or consent agreement to such substance or mixture or repeals the rule or order or modifies the consent agreement to terminate the requirement.

**(c) Exemption**

(1) Any person required by a rule or order under subsection (a) to conduct tests and submit information on a chemical substance or mixture may apply to the Administrator (in such form and manner as the Administrator shall prescribe) for an exemption from such requirement.

(2) If, upon receipt of an application under paragraph (1), the Administrator determines that—

(A) the chemical substance or mixture with respect to which such application was submitted is equivalent to a chemical substance or mixture for which information has been submitted to the Administrator in accordance with a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement, and

(B) submission of information by the applicant on such substance or mixture would be duplicative of information which has been submitted to the Administrator in accordance with such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement,

the Administrator shall exempt, in accordance with paragraph (3) or (4), the applicant from conducting tests and submitting information on such substance or mixture under the rule or order with respect to which such application was submitted.

(3)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information on a chemical substance or mixture is granted on the basis of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information (as prescribed by subparagraph (B)), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted such information, for a portion of the costs incurred by such person in complying with the requirement to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the person to be reimbursed and the share of the market for such substance or mixture of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) For purposes of subparagraph (A), the reimbursement period for any information for a chemical substance or mixture is a period—

(i) beginning on the date such information is submitted in accordance with a rule, order, or consent agreement under subsection (a), and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and which is equal to the period which the Administrator determines was necessary to develop such information,

whichever is later.

(4)(A) If the exemption under paragraph (2) of any person from the requirement to conduct tests and submit information on a chemical substance or mixture is granted on the basis of the fact that information is being developed by one or more persons pursuant to a rule, order, or consent agreement under subsection (a), then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to each such person who is developing such information, for a portion of the costs incurred by each such person in complying with such rule, order, or consent agreement, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to the costs of complying with such rule, order, or consent agreement, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance or mixture,

the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider the factors described in the second sentence of paragraph (3)(A). An order under this subparagraph shall, for purposes of judicial review, be considered final agency action.

(B) If any exemption is granted under paragraph (2) on the basis of the fact that one or more persons are developing information pursuant to a rule, order, or consent agreement under subsection (a) and if after such exemption is granted the Administrator determines that no such person has complied with such rule, order, or consent agreement, the Administrator shall (i) after providing written notice to the person who holds such exemption and an opportunity for a hearing, by order terminate such exemption, and (ii) notify in writing such person of the requirements of the rule or order with respect to which such exemption was granted.

**(d) Notice**

Upon the receipt of any information pursuant to a rule, order, or consent agreement under subsection (a), the Administrator shall publish a notice of the receipt of such information in the Federal Register within 15 days of its receipt. Subject to section 2613 of this title, each such notice shall (1) identify the chemical substance or mixture for which information has been received; (2) list the uses or intended uses of such substance or mixture and the information required by the applicable protocols and methodologies for the development of information; and (3) describe the nature of the information developed. Except as otherwise provided in section 2613 of this title, such information shall be made available by the Administrator for examination by any person.

**(e) Priority list**

(1)(A) There is established a committee to make recommendations to the Administrator respecting the chemical substances and mixtures to which the Administrator should give priority consideration for the development of information under subsection (a). In making such a recommendation with respect to any chemical substance or mixture, the committee shall consider all relevant factors, including—

(i) the quantities in which the substance or mixture is or will be manufactured,

(ii) the quantities in which the substance or mixture enters or will enter the environment,

(iii) the number of individuals who are or will be exposed to the substance or mixture in their places of employment and the duration of such exposure,

(iv) the extent to which human beings are or will be exposed to the substance or mixture,

(v) the extent to which the substance or mixture is closely related to a chemical substance or mixture which is known to present an unreasonable risk of injury to health or the environment,

(vi) the existence of information concerning the effects of the substance or mixture on health or the environment,

(vii) the extent to which testing of the substance or mixture may result in the development of information upon which the effects of

the substance or mixture on health or the environment can reasonably be determined or predicted, and

(viii) the reasonably foreseeable availability of facilities and personnel for performing testing on the substance or mixture.

The recommendations of the committee shall be in the form of a list of chemical substances and mixtures which shall be set forth, either by individual substance or mixture or by groups of substances or mixtures, in the order in which the committee determines the Administrator should take action under subsection (a) with respect to the substances and mixtures. In establishing such list, the committee shall give priority attention to those chemical substances and mixtures which are known to cause or contribute to or which are suspected of causing or contributing to cancer, gene mutations, or birth defects. The committee shall designate chemical substances and mixtures on the list with respect to which the committee determines the Administrator should, within 12 months of the date on which such substances and mixtures are first designated, initiate a proceeding under subsection (a). The total number of chemical substances and mixtures on the list which are designated under the preceding sentence may not, at any time, exceed 50.

(B) As soon as practicable but not later than nine months after January 1, 1977, the committee shall publish in the Federal Register and transmit to the Administrator the list and designations required by subparagraph (A) together with the reasons for the committee's inclusion of each chemical substance or mixture on the list. At least every six months after the date of the transmission to the Administrator of the list pursuant to the preceding<sup>1</sup> sentence, the committee shall make such revisions in the list as it determines to be necessary and shall transmit them to the Administrator together with the committee's reasons for the revisions. Upon receipt of any such revision, the Administrator shall publish in the Federal Register the list with such revision, the reasons for such revision, and the designations made under subparagraph (A). The Administrator shall provide reasonable opportunity to any interested person to file with the Administrator written comments on the committee's list, any revision of such list by the committee, and designations made by the committee, and shall make such comments available to the public. Within the 12-month period beginning on the date of the first inclusion on the list of a chemical substance or mixture designated by the committee under subparagraph (A) the Administrator shall with respect to such chemical substance or mixture issue an order, enter into a consent agreement, or initiate a rule-making proceeding under subsection (a), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding.

(2)(A) The committee established by paragraph (1)(A) shall consist of ten members as follows:

(i) One member appointed by the Administrator from the Environmental Protection Agency.

(ii) One member appointed by the Secretary of Labor from officers or employees of the Department of Labor engaged in the Secretary's activities under the Occupational Safety and Health Act of 1970 [29 U.S.C. 651 et seq.].

(iii) One member appointed by the Chairman of the Council on Environmental Quality from the Council or its officers or employees.

(iv) One member appointed by the Director of the National Institute for Occupational Safety and Health from officers or employees of the Institute.

(v) One member appointed by the Director of the National Institute of Environmental Health Sciences from officers or employees of the Institute.

(vi) One member appointed by the Director of the National Cancer Institute from officers or employees of the Institute.

(vii) One member appointed by the Director of the National Science Foundation from officers or employees of the Foundation.

(viii) One member appointed by the Secretary of Commerce from officers or employees of the Department of Commerce.

(ix) One member appointed by the Chairman of the Consumer Product Safety Commission from Commissioners or employees of the Commission.

(x) One member appointed by the Commissioner of Food and Drugs from employees of the Food and Drug Administration.

(B)(i) An appointed member may designate an individual to serve on the committee on the member's behalf. Such a designation may be made only with the approval of the applicable appointing authority and only if the individual is from the entity from which the member was appointed.

(ii) No individual may serve as a member of the committee for more than four years in the aggregate. If any member of the committee leaves the entity from which the member was appointed, such member may not continue as a member of the committee, and the member's position shall be considered to be vacant. A vacancy in the committee shall be filled in the same manner in which the original appointment was made.

(iii) Initial appointments to the committee shall be made not later than the 60th day after January 1, 1977. Not later than the 90th day after such date the members of the committee shall hold a meeting for the selection of a chairperson from among their number.

(C)(i) No member of the committee, or designee of such member, shall accept employment or compensation from any person subject to any requirement of this chapter or of any rule promulgated or order issued thereunder, for a period of at least 12 months after termination of service on the committee.

(ii) No person, while serving as a member of the committee, or designee of such member, may own any stocks or bonds, or have any pecuniary interest, of substantial value in any person engaged in the manufacture, processing, or distribution in commerce of any chemical sub-

<sup>1</sup> So in original. Probably should be "preceding".

stance or mixture subject to any requirement of this chapter or of any rule promulgated or order issued thereunder.

(iii) The Administrator, acting through attorneys of the Environmental Protection Agency, or the Attorney General may bring an action in the appropriate district court of the United States to restrain any violation of this subparagraph.

(D) The Administrator shall provide the committee such administrative support services as may be necessary to enable the committee to carry out its function under this subsection.

**(f) Required actions**

Upon the receipt of—

(1) any information required to be submitted under this chapter, or

(2) any other information available to the Administrator,

which indicates to the Administrator that there may be a reasonable basis to conclude that a chemical substance or mixture presents a significant risk of serious or widespread harm to human beings, the Administrator shall, within the 180-day period beginning on the date of the receipt of such information, initiate applicable action under section 2604, 2605, or 2606 of this title to prevent or reduce to a sufficient extent such risk or publish in the Federal Register a finding, made without consideration of costs or other nonrisk factors, that such risk is not unreasonable. For good cause shown the Administrator may extend such period for an additional period of not more than 90 days. The Administrator shall publish in the Federal Register notice of any such extension and the reasons therefor. A finding by the Administrator that a risk is not unreasonable shall be considered agency action for purposes of judicial review under chapter 7 of title 5. This subsection shall not take effect until two years after January 1, 1977.

**(g) Petition for protocols and methodologies for the development of information**

A person intending to manufacture or process a chemical substance for which notice is required under section 2604(a) of this title and who is not required under a rule, order, or consent agreement under subsection (a) to conduct tests and submit information on such substance may petition the Administrator to prescribe protocols and methodologies for the development of information for such substance. The Administrator shall by order either grant or deny any such petition within 60 days of its receipt. If the petition is granted, the Administrator shall prescribe such protocols and methodologies for such substance within 75 days of the date the petition is granted. If the petition is denied, the Administrator shall publish, subject to section 2613 of this title, in the Federal Register the reasons for such denial.

**(h) Reduction of testing on vertebrates**

**(1) In general**

The Administrator shall reduce and replace, to the extent practicable, scientifically justified, and consistent with the policies of this subchapter, the use of vertebrate animals in the testing of chemical substances or mixtures under this subchapter by—

(A) prior to making a request or adopting a requirement for testing using vertebrate animals, and in accordance with subsection (a)(3), taking into consideration, as appropriate and to the extent practicable and scientifically justified, reasonably available existing information, including—

(i) toxicity information;

(ii) computational toxicology and bioinformatics; and

(iii) high-throughput screening methods and the prediction models of those methods; and

(B) encouraging and facilitating—

(i) the use of scientifically valid test methods and strategies that reduce or replace the use of vertebrate animals while providing information of equivalent or better scientific quality and relevance that will support regulatory decisions under this subchapter;

(ii) the grouping of 2 or more chemical substances into scientifically appropriate categories in cases in which testing of a chemical substance would provide scientifically valid and useful information on other chemical substances in the category; and

(iii) the formation of industry consortia to jointly conduct testing to avoid unnecessary duplication of tests, provided that such consortia make all information from such testing available to the Administrator.

**(2) Implementation of alternative testing methods**

To promote the development and timely incorporation of new scientifically valid test methods and strategies that are not based on vertebrate animals, the Administrator shall—

(A) not later than 2 years after June 22, 2016, develop a strategic plan to promote the development and implementation of alternative test methods and strategies to reduce, refine, or replace vertebrate animal testing and provide information of equivalent or better scientific quality and relevance for assessing risks of injury to health or the environment of chemical substances or mixtures through, for example—

(i) computational toxicology and bioinformatics;

(ii) high-throughput screening methods;

(iii) testing of categories of chemical substances;

(iv) tiered testing methods;

(v) in vitro studies;

(vi) systems biology;

(vii) new or revised methods identified by validation bodies such as the Interagency Coordinating Committee on the Validation of Alternative Methods or the Organization for Economic Co-operation and Development; or

(viii) industry consortia that develop information submitted under this subchapter;

(B) as practicable, ensure that the strategic plan developed under subparagraph (A) is

reflected in the development of requirements for testing under this section;

(C) include in the strategic plan developed under subparagraph (A) a list, which the Administrator shall update on a regular basis, of particular alternative test methods or strategies the Administrator has identified that do not require new vertebrate animal testing and are scientifically reliable, relevant, and capable of providing information of equivalent or better scientific reliability and quality to that which would be obtained from vertebrate animal testing;

(D) provide an opportunity for public notice and comment on the contents of the plan developed under subparagraph (A), including the criteria for considering scientific reliability and relevance of the test methods and strategies that may be identified pursuant to subparagraph (C);

(E) beginning on the date that is 5 years after June 22, 2016, and every 5 years thereafter, submit to Congress a report that describes the progress made in implementing the plan developed under subparagraph (A) and goals for future alternative test methods and strategies implementation; and

(F) prioritize and, to the extent consistent with available resources and the Administrator's other responsibilities under this subchapter, carry out performance assessment, validation, and translational studies to accelerate the development of scientifically valid test methods and strategies that reduce, refine, or replace the use of vertebrate animals, including minimizing duplication, in any testing under this subchapter.

### (3) Voluntary testing

#### (A) In general

Any person developing information for submission under this subchapter on a voluntary basis and not pursuant to any request or requirement by the Administrator shall first attempt to develop the information by means of an alternative test method or strategy identified by the Administrator pursuant to paragraph (2)(C), if the Administrator has identified such a test method or strategy for the development of such information, before conducting new vertebrate animal testing.

#### (B) Effect of paragraph

Nothing in this paragraph shall, under any circumstance, limit or restrict the submission of any existing information to the Administrator.

#### (C) Relationship to other law

A violation of this paragraph shall not be a prohibited act under section 2614 of this title.

#### (D) Review of means

This paragraph authorizes, but does not require, the Administrator to review the means by which a person conducted testing described in subparagraph (A).

(Pub. L. 94-469, title I, § 4, Oct. 11, 1976, 90 Stat. 2006; renumbered title I, Pub. L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L.

114-182, title I, §§ 4, 19(d), June 22, 2016, 130 Stat. 449, 505.)

#### REFERENCES IN TEXT

The Occupational Safety and Health Act of 1970, referred to in text, is Pub. L. 91-596, Dec. 29, 1970, 84 Stat. 1590, as amended, which is classified principally to chapter 15 (§ 651 et seq.) of Title 29, Labor. For complete classification of this Act to the Code, see Short Title note set out under section 651 of Title 29 and Tables.

#### AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114-182, § 4(2)(B)(x), in concluding provisions, inserted “, or, in the case of a chemical substance or mixture described in subparagraph (A)(i), by rule, order, or consent agreement,” after “shall by rule”, substituted “information” for “data” in two places, and substituted “and which is relevant” for “and which are relevant”.

Pub. L. 114-182, § 4(2)(B)(v), substituted “such information” for “such data” in two places.

Pub. L. 114-182, § 4(2)(B)(iii), substituted “there is insufficient information” for “there are insufficient data” in two places.

Pub. L. 114-182, § 4(2)(A), substituted “(1) If the Administrator finds” for “If the Administrator finds”.

Subsec. (a)(1)(A)(i)(I). Pub. L. 114-182, § 4(2)(B)(i), substituted “(A)(i)(I)” for “(1)(A)(i)”.

Subsec. (a)(1)(A)(i)(II). Pub. L. 114-182, § 4(2)(B)(ii), substituted “(II)” for “(i)”.

Subsec. (a)(1)(A)(i)(III). Pub. L. 114-182, § 4(2)(B)(iv), substituted “(III)” for “(iii)”.

Subsec. (a)(1)(A)(ii)(I). Pub. L. 114-182, § 4(2)(B)(viii), which directed amendment of subsec. (a)(1) by substituting “(bb)” for “(II)”, was executed by making the substitution in text of subsec. (a)(1)(A)(ii)(I) after “quantities or”, to reflect the probable intent of Congress.

Pub. L. 114-182, § 4(2)(B)(vii), which directed amendment of subsec. (a)(1) by substituting “(aa)” for “(I)”, was executed by making the substitution in text of subsec. (a)(1)(A)(ii)(I) after “quantities, and”, to reflect the probable intent of Congress.

Pub. L. 114-182, § 4(2)(B)(vi), substituted “(ii)(I)” for “(B)(i)”.

Subsec. (a)(1)(A)(ii)(II). Pub. L. 114-182, § 4(2)(B)(ii), substituted “(II)” for “(ii)”.

Subsec. (a)(1)(A)(ii)(III). Pub. L. 114-182, § 4(2)(B)(iv), substituted “(III)” for “(iii)”.

Subsec. (a)(1)(B). Pub. L. 114-182, § 4(2)(B)(ix), substituted “(B)” for “(2)”. Former subpar. (B) redesignated subpar. (A)(ii).

Subsec. (a)(2) to (4). Pub. L. 114-182, § 4(2)(C), added pars. (2) to (4). Former par. (2) redesignated par. (1)(B).

Subsec. (b). Pub. L. 114-182, § 19(d)(1)(A)(i), which directed amendment of subsec. (b)(1) by inserting “, order, or consent agreement” at end of paragraph heading, was executed by making the insertion at end of subsec. (b) heading to reflect the probable intent of Congress.

Pub. L. 114-182, § 4(1), substituted “protocols and methodologies” for “standards” wherever appearing except after “various test” in concluding provisions of par. (1).

Subsec. (b)(1). Pub. L. 114-182, § 19(d)(1)(A)(ii), substituted “rule, order, or consent agreement” for “rule” wherever appearing.

Pub. L. 114-182, § 4(3)(A)(iii), substituted “information” for “data” in concluding provisions.

Subsec. (b)(1)(B). Pub. L. 114-182, § 4(3)(A)(i), substituted “information” for “test data”.

Subsec. (b)(1)(C). Pub. L. 114-182, § 4(3)(A)(ii), substituted “information” for “data”.

Subsec. (b)(2)(A). Pub. L. 114-182, § 4(3)(B)(1), inserted “Protocols and methodologies for the development of information may also be prescribed for the assessment of exposure or exposure potential to humans or the environment.” after “health or the environment.” and substituted “information may be” for “test data may be” and “tiered testing” for “hierarchical tests”.

Subsec. (b)(2)(B). Pub. L. 114-182, §19(d)(1)(B), substituted "rules, orders, and consent agreements" for "rules".

Pub. L. 114-182, §4(3)(B)(ii), substituted "information" for "data".

Subsec. (b)(3). Pub. L. 114-182, §4(3)(C)(i), substituted "information" for "data" wherever appearing in subpars. (A) and (B).

Subsec. (b)(3)(A). Pub. L. 114-182, §19(d)(1)(C), substituted "rule or order" for "rule".

Pub. L. 114-182, §4(3)(C)(ii), inserted "or (C), as applicable," after "subparagraph (B)".

Subsec. (b)(3)(B). Pub. L. 114-182, §4(3)(C)(iv), substituted "subsection (a)(1)" for "subsection (a)" in introductory provisions.

Pub. L. 114-182, §4(3)(C)(iii), substituted "(a)(1)(A)(i)(II) or (a)(1)(A)(ii)(II)" for "(a)(1)(A)(ii) or (a)(1)(B)(ii)" in cls. (i) to (iii).

Subsec. (b)(3)(C). Pub. L. 114-182, §4(3)(C)(v), added subpar. (C).

Subsec. (b)(4). Pub. L. 114-182, §19(d)(1)(D), substituted "rule, order, or consent agreement under subsection (a)" for "rule under subsection (a)" in two places, "repeals the rule or order or modifies the consent agreement to terminate the requirement" for "repeals the rule" in two places, and "repeals or modifies the application of the rule, order, or consent agreement" for "repeals the application of the rule".

Pub. L. 114-182, §4(3)(D), substituted "of information" for "of data" in two places and "to information" for "to test data" in two places.

Subsec. (b)(5). Pub. L. 114-182, §4(3)(E), struck out par. (5) which read as follows: "Rules issued under subsection (a) (and any substantive amendment thereto or repeal thereof) shall be promulgated pursuant to section 553 of title 5 except that (A) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions; (B) a transcript shall be made of any oral presentation; and (C) the Administrator shall make and publish with the rule the findings described in paragraph (1)(A) or (1)(B) of subsection (a) and, in the case of a rule respecting a mixture, the finding described in paragraph (2) of such subsection."

Subsec. (c)(1). Pub. L. 114-182, §19(d)(2)(A), substituted "rule or order" for "rule".

Pub. L. 114-182, §4(4)(A), substituted "information" for "data".

Subsec. (c)(2). Pub. L. 114-182, §19(d)(2)(B)(iii), substituted "the rule or order" for "the rule" in concluding provisions.

Pub. L. 114-182, §4(4)(B), substituted "information" for "data" wherever appearing.

Subsec. (c)(2)(A). Pub. L. 114-182, §19(d)(2)(B)(i), substituted "a rule, order, or consent agreement under subsection (a) or for which information is being developed pursuant to such a rule, order, or consent agreement" for "a rule under subsection (a) or for which data is being developed pursuant to such a rule". Amendment was executed as if the amendment by Pub. L. 114-182, §4(4)(B), had not applied, to reflect the probable intent of Congress. See above.

Subsec. (c)(2)(B). Pub. L. 114-182, §19(d)(2)(B)(ii), substituted "such rule, order, or consent agreement or which is being developed pursuant to such rule, order, or consent agreement" for "such rule or which is being developed pursuant to such rule".

Subsec. (c)(3)(A). Pub. L. 114-182, §4(4)(C)(i), substituted "information" for "test data" wherever appearing.

Subsec. (c)(3)(A)(i). Pub. L. 114-182, §4(4)(C), substituted "submitted such information" for "submitted such test data" and "submit such information" for "submit such data".

Subsec. (c)(3)(B). Pub. L. 114-182, §4(4)(C)(i), substituted "information" for "test data" in introductory provisions.

Subsec. (c)(3)(B)(i). Pub. L. 114-182, §19(d)(2)(C), substituted "rule, order, or consent agreement" for "rule promulgated".

Pub. L. 114-182, §4(4)(C)(ii), substituted "such information" for "such data".

Subsec. (c)(3)(B)(ii)(II). Pub. L. 114-182, §4(4)(C)(ii), substituted "such information" for "such data".

Subsec. (c)(4). Pub. L. 114-182, §19(d)(2)(D)(i), (ii), substituted "pursuant to a rule, order, or consent agreement" for "pursuant to a rule promulgated" in two places and "such rule, order, or consent agreement" for "such rule" wherever appearing.

Pub. L. 114-182, §4(4)(D), substituted "information" for "test data" wherever appearing.

Subsec. (c)(4)(B). Pub. L. 114-182, §19(d)(2)(D)(iii), substituted "the rule or order" for "the rule".

Subsec. (d). Pub. L. 114-182, §19(d)(3), substituted "rule, order, or consent agreement" for "rule".

Pub. L. 114-182, §4(5), substituted "any information" for "any test data", "development of information" for "development of test data", "nature of the information" for "nature of the test data", and "for which information has" for "for which data have", and substituted "such information" for "such data" in two places.

Pub. L. 114-182, §4(1), substituted "protocols and methodologies" for "standards".

Subsec. (e)(1)(A). Pub. L. 114-182, §4(6)(A)(i)(I), substituted "development of information" for "promulgation of a rule" in introductory provisions.

Subsec. (e)(1)(A)(vi), (vii). Pub. L. 114-182, §4(6)(A)(i)(II), substituted "information" for "data".

Subsec. (e)(1)(B). Pub. L. 114-182, §4(6)(A)(ii), substituted "issue an order, enter into a consent agreement, or initiate a rulemaking proceeding under subsection (a), or, if such an order or consent agreement is not issued or such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not issuing such an order, entering into such a consent agreement, or initiating such a proceeding" for "either initiate a rulemaking proceeding under subsection (a) or if such a proceeding is not initiated within such period, publish in the Federal Register the Administrator's reason for not initiating such a proceeding".

Subsec. (e)(2)(A). Pub. L. 114-182, §4(6)(B)(i), substituted "ten members" for "eight members" in introductory provisions.

Subsec. (e)(2)(A)(ix), (x). Pub. L. 114-182, §4(6)(B)(ii), added cls. (ix) and (x).

Subsec. (f). Pub. L. 114-182, §4(7)(B), in concluding provisions, struck out "or will present" after "mixture presents" and "from cancer, gene mutations, or birth defects" after "human beings", substituted "applicable" for "appropriate", and inserted ", made without consideration of costs or other nonrisk factors," after "publish in the Federal Register a finding".

Subsec. (f)(1). Pub. L. 114-182, §4(7)(A), substituted "information" for "test data".

Subsec. (g). Pub. L. 114-182, §19(d)(4), substituted "rule, order, or consent agreement" for "rule".

Pub. L. 114-182, §4(8), substituted "Petition for protocols and methodologies for the development of information" for "Petition for standards for the development of test data" in heading and "submit information" for "submit data" and "development of information" for "development of test data" in text.

Pub. L. 114-182, §4(1), substituted "protocols and methodologies" for "standards" in two places.

Subsec. (h). Pub. L. 114-182, §4(6), added subsec. (h).

#### EFFECTIVE DATE

Section effective Jan. 1, 1977, except as provided in subsec. (f) of this section, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

### § 2604. Manufacturing and processing notices

#### (a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may—

(i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if—

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator—

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including—

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) REVIEW AND DETERMINATION.—Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine—

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii) (I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreason-

able risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) FAILURE TO RENDER DETERMINATION.—

(A) FAILURE TO RENDER DETERMINATION.—If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) LIMITATIONS.—(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) ARTICLE CONSIDERATION.—The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) Submission of information

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is

required to submit information for such substance pursuant to a rule, order, or consent agreement under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If—

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule or order under section 2603 of this title before the submission of such notice,

such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(2)(A) If a person—

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule, order, or consent agreement under section 2603 of this title before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that—

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(A)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including—

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of title 5.

**(c) Extension of review period**

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b). Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

**(d) Content of notice; publications in the Federal Register**

(1) The notice required by subsection (a) shall include—

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information under subsection (b), the Administrator shall publish in the Federal Register a notice which—

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

**(e) Regulation pending development of information**

(1)<sup>1</sup>(A) If the Administrator determines that—

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

(B) An order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the

applicable review period, and (ii) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

**(f) Protection against unreasonable risks**

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)—

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(4) TREATMENT OF NONCONFORMING USES.—Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) WORKPLACE EXPOSURES.—To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

<sup>1</sup>So in original. There is no par. (2).

**(g) Statement on Administrator finding**

If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

**(h) Exemptions**

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes—

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that—

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such

exemption is granted during the reimbursement period for such information, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)—

(i) to the person who previously submitted the information on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information for a chemical substance is a period—

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such information to the Administrator, and

(ii) ending—

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such information,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of—

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as

the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

#### (i) Definitions

(1) For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(2) For purposes of this chapter, the term "requirement" as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term "applicable review period" means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

(Pub. L. 94-469, title I, § 5, Oct. 11, 1976, 90 Stat. 2012; renumbered title I, Pub. L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114-182, title I, §§ 5, 19(e), June 22, 2016, 130 Stat. 454, 506.)

#### AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114-182, § 5(1)(A), designated existing provisions as subpar. (A) and redesignated former subpars. (A) and (B) as cls. (i) and (ii), respectively; substituted "Except as provided in subparagraph (B) of this paragraph and" for "Except as provided in" in introductory provisions; substituted "significant new use," for "significant new use," at end of cl. (ii); struck out concluding provisions "unless such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of subsection (b)."; and added subpar. (B).

Subsec. (a)(3) to (5). Pub. L. 114-182, § 5(1)(B), added pars. (3) to (5).

Subsec. (b). Pub. L. 114-182, § 5(2)(A), substituted "information" for "test data" in heading.

Subsec. (b)(1)(A). Pub. L. 114-182, § 19(e)(1)(A), substituted "a rule, order, or consent agreement" for "a rule promulgated" and "such rule, order, or consent agreement" for "such rule".

Pub. L. 114-182, § 5(2)(B)(i), substituted "submit information" for "submit test data" and "such information" for "such data".

Subsec. (b)(1)(B). Pub. L. 114-182, § 5(2)(B)(ii), in concluding provisions, substituted "information" for "test data", "subsection (a)(1)(A)(i)" for "subsection (a)(1)(A)", and "subsection (a)(1)(A)(ii)" for "subsection (a)(1)(B)".

Subsec. (b)(1)(B)(ii). Pub. L. 114-182, § 19(e)(1)(B), substituted "rule or order" for "rule promulgated".

Subsec. (b)(2)(A). Pub. L. 114-182, § 5(2)(C)(1)(II), (III), in concluding provisions, substituted "may" for "shall" and "information prescribed" for "data prescribed".

Subsec. (b)(2)(A)(ii). Pub. L. 114-182, § 19(e)(1)(C), substituted "rule, order, or consent agreement" for "rule promulgated".

Pub. L. 114-182, § 5(2)(C)(1)(I), substituted "information" for "test data".

Subsec. (b)(2)(B). Pub. L. 114-182, § 5(2)(C)(1)(I)-(III), in introductory provisions, substituted "Information" for "Data", "be information" for "be data", "the information" for "the data", and "shows" for "show".

Subsec. (b)(2)(B)(i). Pub. L. 114-182, § 5(2)(C)(1)(IV), substituted "subsection (a)(1)(A)(i)" for "subsection (a)(1)(A)".

Subsec. (b)(2)(B)(ii). Pub. L. 114-182, § 5(2)(C)(1)(V), substituted "subsection (a)(1)(A)(ii)" for "subsection (a)(1)(B)".

Subsec. (b)(3). Pub. L. 114-182, § 5(2)(D), substituted "Information" for "Data" and "paragraph (1) or (2) of this subsection or under subsection (e)" for "paragraph (1) or (2)".

Subsec. (b)(4)(A)(i). Pub. L. 114-182, § 5(2)(E)(1), inserted "without consideration of costs or other nonrisk factors" after "health or the environment".

Subsec. (b)(4)(C). Pub. L. 114-182, § 5(2)(E)(1), struck out "except that (i) the Administrator shall give interested persons an opportunity for the oral presentation of data, views, or arguments, in addition to an opportunity to make written submissions, (ii) a transcript shall be kept of any oral presentation, and (iii) the Administrator shall make and publish with the rule the finding described in subparagraph (A)" before period at end.

Subsec. (c). Pub. L. 114-182, § 5(3), substituted "review" for "notice" in heading and struck out "before which the manufacturing or processing of a chemical substance subject to such subsection may begin" after "subsection (a) or (b)" in text.

Subsec. (d)(1)(B). Pub. L. 114-182, § 5(4)(A), substituted "information" for "test data".

Subsec. (d)(1)(C). Pub. L. 114-182, § 5(4)(B), substituted "information" for "data".

Subsec. (d)(2). Pub. L. 114-182, § 5(4)(B), substituted "information" for "data" wherever appearing.

Subsec. (d)(2)(B). Pub. L. 114-182, § 5(4)(C), substituted "uses of such substance identified in the notice" for "uses or intended uses of such substance".

Subsec. (d)(2)(C). Pub. L. 114-182, § 19(e)(2), substituted "rule, order, or consent agreement" for "rule".

Subsec. (d)(3). Pub. L. 114-182, § 5(4)(D), substituted "for which the applicable review period" for "for which the notification period prescribed by subsection (a), (b), or (c)" and "such period" for "such notification period".

Subsec. (e)(1)(A). Pub. L. 114-182, § 5(5)(A)(iii)(III), inserted before period at end of concluding provisions "to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed

or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order".

Pub. L. 114-182, §5(5)(A)(iii)(II), which directed substitution of "applicable review period" for "notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), (c)" in concluding provisions, was executed by making the substitution for "notification period applicable to the manufacturing or processing of such substance under subsection (a), (b), or (c)" to reflect the probable intent of Congress.

Pub. L. 114-182, §5(5)(A)(iii)(I), substituted "shall issue an order" for "may issue a proposed order" in concluding provisions.

Subsec. (e)(1)(A)(i). Pub. L. 114-182, §5(5)(A)(i), substituted "; or" for "; and" at end.

Subsec. (e)(1)(A)(ii)(I). Pub. L. 114-182, §5(5)(A)(ii), inserted "without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use;" after "health or the environment."

Subsec. (e)(1)(B). Pub. L. 114-182, §5(5)(B)(ii), substituted "of the order" for "of the proposed order".

Pub. L. 114-182, §5(5)(B)(ii), which directed substitution of "applicable review period" for "notification period applicable to the manufacture or processing of such substance under subsection (a), (b), (c)", was executed by making the substitution for "notification period applicable to the manufacture or processing of such substance under subsection (a), (b), or (c)" to reflect the probable intent of Congress.

Pub. L. 114-182, §5(5)(B)(i), substituted "An order" for "A proposed order".

Subsec. (e)(1)(C). Pub. L. 114-182, §5(5)(C), struck out subpar. (C) which read as follows: "If a manufacturer or processor of a chemical substance to be subject to a proposed order issued under subparagraph (A) files with the Administrator (within the 30-day period beginning on the date such manufacturer or processor received the notice required by subparagraph (B)(ii)) objections specifying with particularity the provisions of the order deemed objectionable and stating the grounds therefor, the proposed order shall not take effect."

Subsec. (e)(2). Pub. L. 114-182, §5(5)(D), struck out par. (2) which related to injunctions to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance.

Subsec. (f)(1). Pub. L. 114-182, §5(6)(A), substituted "determines that a chemical substance or significant new use with" for "finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance with", "without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use," for "before a rule promulgated under section 2605 of this title can protect against such risk," and "applicable review period" for "notification period applicable under subsection (a), (b), or (c) to the manufacturing or processing of such substance" and struck out "or that any combination of such activities," after "required by subsection (a)" and "or will present" after "presents".

Subsec. (f)(2). Pub. L. 114-182, §5(6)(B), substituted "Section 2605(d)(3)(B)" for "Section 2605(d)(2)(B)" in concluding provisions.

Subsec. (f)(3)(A). Pub. L. 114-182, §5(6)(C)(i), substituted "Administrator may" for "Administrator may—", struck out cl. (i) designation before "issue", substituted "an order to prohibit or limit the" for "a proposed order to prohibit the" and "under paragraph (1). Such order shall take effect on the expiration of the applicable review period." for "under paragraph (1), or", and struck out cl. (ii) and concluding provisions which read as follows:

"(ii) apply, through attorneys of the Environmental Protection Agency, to the United States District Court for the District of Columbia or the United States district court for the judicial district in which the manufacturer, or processor, as the case may be, of such substance, is found, resides, or transacts business for an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance.

A proposed order issued under clause (i) respecting a chemical substance shall take effect on the expiration of the notification period applicable under subsection (a), (b), or (c) to the manufacture or processing of such substance."

Subsec. (f)(3)(B), (C). Pub. L. 114-182, §5(6)(C)(ii), (iii), redesignated subpar. (C) as (B), substituted "subparagraph (B)" for "subparagraphs (B) and (C)", struck out "clause (i) or" after "order issued under" and "; and the provisions of subparagraph (C) of subsection (e)(2) shall apply with respect to an injunction issued under subparagraph (B)" after "subparagraph (A)", and struck out former subpar. (B) which read as follows: "If the district court of the United States to which an application has been made under subparagraph (A)(ii) finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance with respect to which such application was made, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment before a rule promulgated under section 2605 of this title can protect against such risk, the court shall issue an injunction to prohibit the manufacture, processing, or distribution in commerce of such substance or to prohibit any combination of such activities."

Subsec. (f)(3)(D). Pub. L. 114-182, §5(6)(C)(iv), struck out subpar. (D) which read as follows: "If the Administrator issues an order pursuant to subparagraph (A)(i) respecting a chemical substance and objections are filed in accordance with subsection (e)(1)(C), the Administrator shall seek an injunction under subparagraph (A)(ii) respecting such substance unless the Administrator determines, on the basis of such objections, that such substance does not or will not present an unreasonable risk of injury to health or the environment."

Subsec. (f)(4), (5). Pub. L. 114-182, §5(6)(D), added pars. (4) and (5).

Subsec. (g). Pub. L. 114-182, §5(7), amended subsec. (g) generally. Prior to amendment, text read as follows: "If the Administrator has not initiated any action under this section or section 2605 or 2606 of this title to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance, with respect to which notification or data is required by subsection (a)(1)(B) or (b), before the expiration of the notification period applicable to the manufacturing or processing of such substance, the Administrator shall publish a statement of the Administrator's reasons for not initiating such action. Such a statement shall be published in the Federal Register before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published."

Subsec. (h)(1)(A). Pub. L. 114-182, §5(8)(A), inserted "including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application" after "health or the environment".

Subsec. (h)(2). Pub. L. 114-182, §5(8)(B), substituted "information" for "data" wherever appearing.

Subsec. (h)(4). Pub. L. 114-182, §5(8)(C), substituted "environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use" for "environment. A rule promulgated under this paragraph (and any substantive amendment to, or repeal of, such a rule) shall be promulgated in accordance with paragraphs (2) and (3) of section 2605(c) of this title".

Subsec. (1). Pub. L. 114-182, § 5(9), amended subsec. (1) generally. Prior to amendment, text read as follows: "For purposes of this section, the terms 'manufacture' and 'process' mean manufacturing or processing for commercial purposes."

**EFFECTIVE DATE**

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

**§ 2605. Prioritization, risk evaluation, and regulation of chemical substances and mixtures**

**(a) Scope of regulation**

If the Administrator determines in accordance with subsection (b)(4)(A) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule and subject to section 2617 of this title, and in accordance with subsection (c)(2), apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk:

(1) A requirement (A) prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce of such substance or mixture, or (B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce.

(2) A requirement—

(A) prohibiting or otherwise restricting the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement, or

(B) limiting the amount of such substance or mixture which may be manufactured, processed, or distributed in commerce for (i) a particular use or (ii) a particular use in a concentration in excess of a level specified by the Administrator in the rule imposing the requirement.

(3) A requirement that such substance or mixture or any article containing such substance or mixture be marked with or accompanied by clear and adequate minimum warnings and instructions with respect to its use, distribution in commerce, or disposal or with respect to any combination of such activities. The form and content of such minimum warnings and instructions shall be prescribed by the Administrator.

(4) A requirement that manufacturers and processors of such substance or mixture make and retain records of the processes used to manufacture or process such substance or mixture or monitor or conduct tests which are reasonable and necessary to assure compliance with the requirements of any rule applicable under this subsection.

(5) A requirement prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture.

(6)(A) A requirement prohibiting or otherwise regulating any manner or method of dis-

posal of such substance or mixture, or of any article containing such substance or mixture, by its manufacturer or processor or by any other person who uses, or disposes of, it for commercial purposes.

(B) A requirement under subparagraph (A) may not require any person to take any action which would be in violation of any law or requirement of, or in effect for, a State or political subdivision, and shall require each person subject to it to notify each State and political subdivision in which a required disposal may occur of such disposal.

(7) A requirement directing manufacturers or processors of such substance or mixture (A) to give notice of such determination to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (B) to give public notice of such determination, and (C) to replace or repurchase such substance or mixture as elected by the person to which the requirement is directed.

Any requirement (or combination of requirements) imposed under this subsection may be limited in application to specified geographic areas.

**(b) Risk evaluations**

**(1) Prioritization for risk evaluations**

**(A) Establishment of process**

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process, including criteria for designating chemical substances as high-priority substances for risk evaluations or low-priority substances for which risk evaluations are not warranted at the time. The process to designate the priority of chemical substances shall include a consideration of the hazard and exposure potential of a chemical substance or a category of chemical substances (including consideration of persistence and bioaccumulation, potentially exposed or susceptible subpopulations and storage near significant sources of drinking water), the conditions of use or significant changes in the conditions of use of the chemical substance, and the volume or significant changes in the volume of the chemical substance manufactured or processed.

**(B) Identification of priorities for risk evaluation**

**(i) High-priority substances**

The Administrator shall designate as a high-priority substance a chemical substance that the Administrator concludes, without consideration of costs or other nonrisk 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 a potentially exposed or susceptible subpopulation identified as relevant by the Administrator.

by subsection (a) [amending this section] shall cease to have effect on September 30, 2012. The termination of the authority to grant exemptions pursuant to such amendments shall not effect the validity of any exemption granted prior to such date."

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

§ 2606. Imminent hazards

(a) Actions authorized and required

(1) The Administrator may commence a civil action in an appropriate district court of the United States—

(A) for seizure of an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture,

(B) for relief (as authorized by subsection (b)) against any person who manufactures, processes, distributes in commerce, or uses, or disposes of, an imminently hazardous chemical substance or mixture or any article containing such a substance or mixture, or

(C) for both such seizure and relief.

A civil action may be commenced under this paragraph notwithstanding the existence of a determination under section 2604 or 2605 of this title, a rule under section 2603, 2604, or 2605 of this title or subchapter IV, an order under section 2603, 2604, or 2605 of this title or subchapter IV, or a consent agreement under section 2603 of this title, and notwithstanding the pendency of any administrative or judicial proceeding under any provision of this chapter.

(2) If the Administrator has not made a rule under section 2605(a) of this title immediately effective (as authorized by section 2605(d)(3)(A)(1) of this title) with respect to an imminently hazardous chemical substance or mixture, the Administrator shall commence in a district court of the United States with respect to such substance or mixture or article containing such substance or mixture a civil action described in subparagraph (A), (B), or (C) of paragraph (1).

(b) Relief authorized

(1) The district court of the United States in which an action under subsection (a) is brought shall have jurisdiction to grant such temporary or permanent relief as may be necessary to protect health or the environment from the unreasonable risk (as identified by the Administrator without consideration of costs or other nonrisk factors) associated with the chemical substance, mixture, or article involved in such action.

(2) In the case of an action under subsection (a) brought against a person who manufactures, processes, or distributes in commerce a chemical substance or mixture or an article containing a chemical substance or mixture, the relief authorized by paragraph (1) may include the issuance of a mandatory order requiring (A) in the case of purchasers of such substance, mixture, or article known to the defendant, notification to such purchasers of the risk associated with it; (B) public notice of such risk; (C) recall; (D) the replacement or repurchase of such substance, mixture, or article; or (E) any combination of the actions described in the preceding clauses.

(3) In the case of an action under subsection (a) against a chemical substance, mixture, or article, such substance, mixture, or article may be proceeded against by process of libel for its seizure and condemnation. Proceedings in such an action shall conform as nearly as possible to proceedings in rem in admiralty.

(c) Venue and consolidation

(1)(A) An action under subsection (a) against a person who manufactures, processes, or distributes a chemical substance or mixture or an article containing a chemical substance or mixture may be brought in the United States District Court for the District of Columbia or for any judicial district in which any of the defendants is found, resides, or transacts business; and process in such an action may be served on a defendant in any other district in which such defendant resides or may be found. An action under subsection (a) against a chemical substance, mixture, or article may be brought in any United States district court within the jurisdiction of which the substance, mixture, or article is found.

(B) In determining the judicial district in which an action may be brought under subsection (a) in instances in which such action may be brought in more than one judicial district, the Administrator shall take into account the convenience of the parties.

(C) Subpoenas<sup>1</sup> requiring attendance of witnesses in an action brought under subsection (a) may be served in any judicial district.

(2) Whenever proceedings under subsection (a) involving identical chemical substances, mixtures, or articles are pending in courts in two or more judicial districts, they shall be consolidated for trial by order of any such court upon application reasonably made by any party in interest, upon notice to all parties in interest.

(d) Action under section 2605

Where appropriate, concurrently with the filing of an action under subsection (a) or as soon thereafter as may be practicable, the Administrator shall initiate a proceeding for the promulgation of a rule under section 2605(a) of this title.

(e) Representation

Notwithstanding any other provision of law, in any action under subsection (a), the Administrator may direct attorneys of the Environmental Protection Agency to appear and represent the Administrator in such an action.

(f) "Imminently hazardous chemical substance or mixture" defined

For the purposes of subsection (a), the term "imminently hazardous chemical substance or mixture" means a chemical substance or mixture which presents an imminent and unreasonable risk of serious or widespread injury to health or the environment, without consideration of costs or other nonrisk factors. Such a risk to health or the environment shall be considered imminent if it is shown that the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or

<sup>1</sup> So in original. Probably should be "Subpoenas".

mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk.

(Pub. L. 94-469, title I, §7, Oct. 11, 1976, 90 Stat. 2026; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 102-550, title X, §1021(b)(1), Oct. 28, 1992, 106 Stat. 3923; Pub. L. 114-182, title I, §§7, 19(f), June 22, 2016, 130 Stat. 470, 507.)

#### AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114-182, §19(f)(1), in concluding provisions, substituted “a determination under section 2604 or 2605 of this title, a rule under section 2603, 2604, or 2605 of this title or subchapter IV, an order under section 2603, 2604, or 2605 of this title or subchapter IV, or a consent agreement under section 2603 of this title” for “a rule under section 2603 of this title, 2604 of this title, 2605 of this title, or subchapter IV or an order under section 2604 of this title or subchapter IV”.

Subsec. (a)(2). Pub. L. 114-182, §19(f)(2), substituted “section 2605(d)(3)(A)(i)” for “section 2605(d)(2)(A)(i)”.

Subsec. (b)(1). Pub. L. 114-182, §7(1), inserted “(as identified by the Administrator without consideration of costs or other nonrisk factors)” after “from the unreasonable risk”.

Subsec. (f). Pub. L. 114-182, §7(2), inserted “, without consideration of costs or other nonrisk factors” after “widespread injury to health or the environment”.

1992—Subsec. (a)(1). Pub. L. 102-550 substituted “section 2603 of this title, 2604 of this title, 2605 of this title, or subchapter IV” for “section 2603, 2604, or 2605 of this title” in last sentence.

Pub. L. 102-550, which directed the insertion of “or subchapter IV” after “2604”, was executed by making the insertion after “2604” the second time appearing in last sentence, to reflect the probable intent of Congress.

#### EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

### § 2607. Reporting and retention of information

#### (a) Reports

(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the

Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this chapter.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this chapter. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after January 1, 1977.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing information concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 2603, 2604(b)(4), or 2605 of this title,<sup>1</sup> an order in effect under section 2603 or 2604(e) of this title, or a consent agreement under section 2603 of this title, or

<sup>1</sup> So in original.

(II) with respect to which relief has been granted pursuant to a civil action brought under section 2604 or 2606 of this title,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(C) Not later than 180 days after June 22, 2016, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

(i) review the adequacy of the standards prescribed under subparagraph (B); and

(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted.

(4) **CONTENTS.**—The rules promulgated pursuant to paragraph (1)—

(A) may impose differing reporting and recordkeeping requirements on manufacturers and processors; and

(B) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

(5) **ADMINISTRATION.**—In carrying out this section, the Administrator shall, to the extent feasible—

(A) not require reporting which is unnecessary or duplicative;

(B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and

(C) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this subchapter.

(6) **NEGOTIATED RULEMAKING.**—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5 to develop and publish, not later than 3 years after June 22, 2016, a proposed rule providing for limiting the reporting requirements, under this subsection, for manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.

(B) Not later than 3 and one-half years after June 22, 2016, the Administrator shall publish a final rule resulting from such negotiated rulemaking.

**(b) Inventory**

(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least in-

clude each chemical substance which any person reports, under section 2604 of this title or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 2604 of this title, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after January 1, 1977. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this chapter, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

**(3) NOMENCLATURE.**—

(A) **IN GENERAL.**—In carrying out paragraph (1), the Administrator shall—

(i) maintain the use of Class 2 nomenclature in use on June 22, 2016;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled "Candidate List of Chemical Substances", and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA-560/7-85-002a); and

(iii) treat the individual members of the categories of chemical substances identified by the Administrator as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the list established under paragraph (1).

(B) **MULTIPLE NOMENCLATURE LISTINGS.**—If a manufacturer or processor demonstrates to the Administrator that a chemical substance appears multiple times on the list published under paragraph (1) under different CAS numbers, the Administrator may recognize the multiple listings as a single chemical substance.

**(4) CHEMICAL SUBSTANCES IN COMMERCE.**—

**(A) RULES.**—

(1) **IN GENERAL.**—Not later than 1 year after June 22, 2016, the Administrator, by rule, shall require manufacturers, and may require processors, subject to the limitations under subsection (a)(5)(A), to notify the Administrator, by not later than 180 days after

the date on which the final rule is published in the Federal Register, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before June 22, 2016.

(ii) **ACTIVE SUBSTANCES.**—The Administrator shall designate chemical substances for which notices are received under clause (1) to be active substances on the list published under paragraph (1).

(iii) **INACTIVE SUBSTANCES.**—The Administrator shall designate chemical substances for which no notices are received under clause (1) to be inactive substances on the list published under paragraph (1).

(iv) **LIMITATION.**—No chemical substance on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph, or be subject to section 2604(a)(1)(A)(i) of this title by reason of a change to active status under paragraph (5)(B).

(B) **CONFIDENTIAL CHEMICAL SUBSTANCES.**—In promulgating a rule under subparagraph (A), the Administrator shall—

(i) maintain the list under paragraph (1), which shall include a confidential portion and a nonconfidential portion consistent with this section and section 2613 of this title;

(ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential pursuant to section 2613 of this title to submit a notice under subparagraph (A) that includes such request;

(iii) require the substantiation of those claims pursuant to section 2613 of this title and in accordance with the review plan described in subparagraph (C); and

(iv) move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list.

(C) **REVIEW PLAN.**—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B).

(D) **REQUIREMENTS OF REVIEW PLAN.**—In establishing the review plan under subparagraph (C), the Administrator shall—

(i) require, at a time specified by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to

substantiate the claim, in accordance with section 2613 of this title, unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the last day of the of the time period specified by the Administrator; and

(ii) in accordance with section 2613 of this title—

(I) review each substantiation—

(aa) submitted pursuant to clause (1) to determine if the claim qualifies for protection from disclosure; and

(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

(II) approve, approve in part and deny in part, or deny each claim; and

(III) except as provided in this section and section 2613 of this title, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall not protect the information from disclosure; or

(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 2613(g)(2) of this title.

(E) **TIMELINE FOR COMPLETION OF REVIEWS.**—

(i) **IN GENERAL.**—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

(ii) **CONSIDERATIONS.**—

(I) **IN GENERAL.**—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of claims needing review and the available resources.

(II) **ANNUAL REVIEW GOAL AND RESULTS.**—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

(5) **ACTIVE AND INACTIVE SUBSTANCES.**—

(A) **IN GENERAL.**—The Administrator shall keep designations of active substances and inactive substances on the list published under paragraph (1) current.

(B) **CHANGE TO ACTIVE STATUS.**—

(i) **IN GENERAL.**—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance

that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

(i) **CONFIDENTIAL CHEMICAL IDENTITY.**—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the inactive substance as confidential, the person shall, consistent with the requirements of section 2613 of this title—

(I) in the notice submitted under clause (i), assert the claim; and

(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

(iii) **ACTIVE STATUS.**—On receiving a notification under clause (i), the Administrator shall—

(I) designate the applicable chemical substance as an active substance;

(II) pursuant to section 2613 of this title, promptly review any claim and associated substantiation submitted pursuant to clause (i) for protection against disclosure of the specific chemical identity of the chemical substance and approve, approve in part and deny in part, or deny the claim;

(III) except as provided in this section and section 2613 of this title, protect from disclosure the specific chemical identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall not protect the information from disclosure; or

(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 2613(g)(2) of this title; and

(IV) pursuant to section 2605(b) of this title, review the priority of the chemical substance as the Administrator determines to be necessary.

(C) **CATEGORY STATUS.**—The list of inactive substances shall not be considered to be a category for purposes of section 2625(c) of this title.

(6) **INTERIM LIST OF ACTIVE SUBSTANCES.**—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on June 22, 2016), during the reporting period that most closely preceded June 22, 2016, as the interim list of active substances for the purposes of section 2605(b) of this title.

(7) **PUBLIC INFORMATION.**—Subject to this subsection and section 2613 of this title, the Administrator shall make available to the public—

(A) each specific chemical identity on the nonconfidential portion of the list published under paragraph (1) along with the Administrator's designation of the chemical substance as an active or inactive substance;

(B) the unique identifier assigned under section 2613 of this title, accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

(C) the specific chemical identity of any active substance for which—

(i) a claim for protection against disclosure of the specific chemical identity of the active substance was not asserted, as required under this subsection or section 2613 of this title;

(ii) all claims for protection against disclosure of the specific chemical identity of the active substance have been denied by the Administrator; or

(iii) the time period for protection against disclosure of the specific chemical identity of the active substance has expired.

(8) **LIMITATION.**—No person may assert a new claim under this subsection or section 2613 of this title for protection from disclosure of a specific chemical identity of any active or inactive substance for which a notice is received under paragraph (4)(A)(i) or (5)(B)(i) that is not on the confidential portion of the list published under paragraph (1).

(9) **CERTIFICATION.**—Under the rules promulgated under this subsection, manufacturers and processors, as applicable, shall be required—

(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

(B) to retain a record documenting compliance with the rule and supporting confidentiality claims for a period of 5 years beginning on the last day of the submission period.

(10) **MERCURY.**—

(A) **DEFINITION OF MERCURY.**—In this paragraph, notwithstanding section 2602(2)(B) of this title, the term “mercury” means—

- (i) elemental mercury; and
- (ii) a mercury compound.

(B) **PUBLICATION.**—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

(C) **PROCESS.**—In carrying out the inventory under subparagraph (B), the Administrator shall—

(i) identify any manufacturing processes or products that intentionally add mercury; and

(ii) recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.

(D) **REPORTING.**—

(i) **IN GENERAL.**—To assist in the preparation of the inventory under subparagraph

(B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after June 22, 2016.

(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

(iii) EXEMPTION.—Clause (i) shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.

#### (c) Records

Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

#### (d) Health and safety studies

The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this chapter; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

#### (e) Notice to Administrator of substantial risks

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

#### (f) "Manufacture" and "process" defined

For purposes of this section, the terms "manufacture" and "process" mean manufacture or process for commercial purposes.

(Pub. L. 94-469, title I, § 8, Oct. 11, 1976, 90 Stat. 2027; renumbered title I, Pub. L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114-182, title I, §§ 8, 19(g), June 22, 2016, 130 Stat. 470, 507.)

#### AMENDMENTS

2016—Subsec. (a)(2). Pub. L. 114-182, § 8(a)(1)(A), struck out concluding provisions which read as follows: "To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative."

Subsec. (a)(2)(B). Pub. L. 114-182, § 19(g)(1), substituted "information" for "data".

Subsec. (a)(3)(A)(ii)(I). Pub. L. 114-182, § 19(g)(2), substituted "an order in effect under section 2603 or 2604(e) of this title, or a consent agreement under section 2603 of this title" for "or an order in effect under section 2604(e) of this title".

Subsec. (a)(3)(C). Pub. L. 114-182, § 8(a)(1)(B), added subpar. (C).

Subsec. (a)(4) to (6). Pub. L. 114-182, § 8(a)(1)(C), added pars. (4) to (6).

Subsec. (b)(3) to (9). Pub. L. 114-182, § 8(a)(2), added pars. (3) to (9).

Subsec. (b)(10). Pub. L. 114-182, § 8(b), added par. (10).

#### EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

#### ASBESTOS INFORMATION

Pub. L. 100-577, Oct. 31, 1988, 102 Stat. 2901, provided that:

#### "SECTION 1. SHORT TITLE.

"This Act may be cited as the 'Asbestos Information Act of 1988'.

#### "SEC. 2. SUBMISSION OF INFORMATION BY MANUFACTURERS.

"Within 90 days after the date of the enactment of this Act [Oct. 31, 1988], any person who manufactured or processed, before the date of the enactment of this Act, asbestos or asbestos-containing material that was prepared for sale for use as surfacing material, thermal system insulation, or miscellaneous material in buildings (or whose corporate predecessor manufactured or processed such asbestos or material) shall submit to the Administrator of the Environmental Protection Agency the years of manufacture, the types or classes of product, and, to the extent available, other identifying characteristics reasonably necessary to identify or distinguish the asbestos or asbestos-containing material. Such person also may submit to the Administrator protocols for samples of asbestos and asbestos-containing material.

#### "SEC. 3. PUBLICATION OF INFORMATION.

"Within 30 days after the date of the enactment of this Act [Oct. 31, 1988], the Administrator shall publish

**§ 2616. Specific enforcement and seizure****(a) Specific enforcement**

(1) The district courts of the United States shall have jurisdiction over civil actions to—

(A) restrain any violation of section 2614 or 2689 of this title,

(B) restrain any person from taking any action prohibited by section 2604 of this title, 2605 of this title, or subchapter IV, or by a rule or order under section 2604 of this title, 2605 of this title, or subchapter IV,

(C) compel the taking of any action required by or under this chapter, or

(D) direct any manufacturer or processor of a chemical substance, mixture, or product subject to subchapter IV manufactured or processed in violation of section 2604 of this title, 2605 of this title, or subchapter IV, or a rule or order under section 2604 of this title, 2605 of this title, or subchapter IV, and distributed in commerce, (i) to give notice of such fact to distributors in commerce of such substance, mixture, or product and, to the extent reasonably ascertainable, to other persons in possession of such substance, mixture, or product or exposed to such substance, mixture, or product, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance, mixture, or product, whichever the person to which the requirement is directed elects.

(2) A civil action described in paragraph (1) may be brought—

(A) in the case of a civil action described in subparagraph (A) of such paragraph, in the United States district court for the judicial district wherein any act, omission, or transaction constituting a violation of section 2614 of this title occurred or wherein the defendant is found or transacts business, or

(B) in the case of any other civil action described in such paragraph, in the United States district court for the judicial district wherein the defendant is found or transacts business.

In any such civil action process may be served on a defendant in any judicial district in which a defendant resides or may be found. Subpoenas requiring attendance of witnesses in any such action may be served in any judicial district.

**(b) Seizure**

Any chemical substance, mixture, or product subject to subchapter IV which was manufactured, processed, or distributed in commerce in violation of this chapter or any rule promulgated or order issued under this chapter or any article containing such a substance or mixture shall be liable to be proceeded against, by process of libel, for the seizure and condemnation of such substance, mixture, product, or article, in any district court of the United States within the jurisdiction of which such substance, mixture, product, or article is found. Such proceedings shall conform as nearly as possible to proceedings in rem in admiralty.

(Pub. L. 94-469, title I, §17, Oct. 11, 1976, 90 Stat. 2037; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L.

102-550, title X, §1021(b)(6), (7), Oct. 28, 1992, 106 Stat. 3923.)

## AMENDMENTS

1992—Subsec. (a). Pub. L. 102-550, §1021(b)(6), which directed that subsec. (a) be amended "to read as follows" and then set out the subsec. (a) designation and heading, followed by the par. (1) designation and text, without any restatement of par. (2), was executed as a general amendment of par. (1) only, to reflect the probable intent of Congress. Prior to amendment, par. (1) read as follows: "The district courts of the United States shall have jurisdiction over civil actions to—

"(A) restrain any violation of section 2614 of this title,

"(B) restrain any person from taking any action prohibited by section 2604 or 2605 of this title or by a rule or order under section 2604 or 2605 of this title,

"(C) compel the taking of any action required by or under this chapter, or

"(D) direct any manufacturer or processor of a chemical substance or mixture manufactured or processed in violation of section 2604 or 2605 of this title or a rule or order under section 2604 or 2605 of this title and distributed in commerce, (i) to give notice of such fact to distributors in commerce of such substance or mixture and, to the extent reasonably ascertainable, to other persons in possession of such substance or mixture or exposed to such substance or mixture, (ii) to give public notice of such risk of injury, and (iii) to either replace or repurchase such substance or mixture, whichever the person to which the requirement is directed elects."

Subsec. (b). Pub. L. 102-550, §1021(b)(7), in first sentence substituted "substance, mixture, or product subject to subchapter IV" for "substance or mixture" and inserted "product," before "or article" in two places.

## EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

**§ 2617. Preemption****(a) In general****(1) Establishment or enforcement**

Except as otherwise provided in subsections (c), (d), (e), (f), and (g), and subject to paragraph (2), no State or political subdivision of a State may establish or continue to enforce any of the following:

**(A) Development of information**

A statute or administrative action to require the development of information about a chemical substance or category of chemical substances that is reasonably likely to produce the same information required under section 2603, 2604, or 2605 of this title in—

(i) a rule promulgated by the Administrator;

(ii) a consent agreement entered into by the Administrator; or

(iii) an order issued by the Administrator.

**(B) Chemical substances found not to present an unreasonable risk or restricted**

A statute, criminal penalty, or administrative action to prohibit or otherwise restrict the manufacture, processing, or distribution in commerce or use of a chemical substance—

(i) for which the determination described in section 2605(i)(1) of this title is made,

consistent with the scope of the risk evaluation under section 2605(b)(4)(D)<sup>1</sup> of this title; or

(ii) for which a final rule is promulgated under section 2605(a) of this title, after the effective date of the rule issued under section 2605(a) of this title for the chemical substance, consistent with the scope of the risk evaluation under section 2605(b)(4)(D)<sup>1</sup> of this title.

**(C) Significant new use**

A statute or administrative action requiring the notification of a use of a chemical substance that the Administrator has specified as a significant new use and for which the Administrator has required notification pursuant to a rule promulgated under section 2604 of this title.

**(2) Effective date of preemption**

Under this subsection, Federal preemption of statutes and administrative actions applicable to specific chemical substances shall not occur until the effective date of the applicable action described in paragraph (1) taken by the Administrator.

**(b) New statutes, criminal penalties, or administrative actions creating prohibitions or other restrictions**

**(1) In general**

Except as provided in subsections (c), (d), (e), (f), and (g), beginning on the date on which the Administrator defines the scope of a risk evaluation for a chemical substance under section 2605(b)(4)(D) of this title and ending on the date on which the deadline established pursuant to section 2605(b)(4)(G) of this title for completion of the risk evaluation expires, or on the date on which the Administrator publishes the risk evaluation under section 2605(b)(4)(C) of this title, whichever is earlier, no State or political subdivision of a State may establish a statute, criminal penalty, or administrative action prohibiting or otherwise restricting the manufacture, processing, distribution in commerce, or use of such chemical substance that is a high-priority substance designated under section 2605(b)(1)(B)(i) of this title.

**(2) Effect of subsection**

This subsection does not restrict the authority of a State or political subdivision of a State to continue to enforce any statute enacted, criminal penalty assessed, or administrative action taken, prior to the date on which the Administrator defines and publishes the scope of a risk evaluation under section 2605(b)(4)(D) of this title.

**(c) Scope of preemption**

Federal preemption under subsections (a) and (b) of statutes, criminal penalties, and administrative actions applicable to specific chemical substances shall apply only to—

(1) with respect to subsection (a)(1)(A), the chemical substances or category of chemical substances subject to a rule, order, or consent

agreement under section 2603, 2604, or 2605 of this title;

(2) with respect to subsection (b), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in the scope of the risk evaluation pursuant to section 2605(b)(4)(D) of this title;

(3) with respect to subsection (a)(1)(B), the hazards, exposures, risks, and uses or conditions of use of such chemical substances included in any final action the Administrator takes pursuant to section 2605(a) or 2605(1)(1) of this title; or

(4) with respect to subsection (a)(1)(C), the uses of such chemical substances that the Administrator has specified as significant new uses and for which the Administrator has required notification pursuant to a rule promulgated under section 2604 of this title.

**(d) Exceptions**

**(1) No preemption of statutes and administrative actions**

**(A) In general**

Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rule, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall affect the right of a State or a political subdivision of a State to adopt or enforce any rule, standard of performance, risk evaluation, scientific assessment, or any other protection for public health or the environment that—

(i) is adopted or authorized under the authority of any other Federal law or adopted to satisfy or obtain authorization or approval under any other Federal law;

(ii) implements a reporting, monitoring, or other information obligation for the chemical substance not otherwise required by the Administrator under this chapter or required under any other Federal law;

(iii) is adopted pursuant to authority under a law of the State or political subdivision of the State related to water quality, air quality, or waste treatment or disposal, except to the extent that the action—

(I) imposes a restriction on the manufacture, processing, distribution in commerce, or use of a chemical substance; and

(II)(aa) addresses the same hazards and exposures, with respect to the same conditions of use as are included in the scope of the risk evaluation published pursuant to section 2605(b)(4)(D) of this title, but is inconsistent with the action of the Administrator; or

(bb) would cause a violation of the applicable action by the Administrator under section 2604 or 2605 of this title; or

(iv) subject to subparagraph (B), is identical to a requirement prescribed by the Administrator.

<sup>1</sup>See References in Text note below.

**(B) Identical requirements****(i) In general**

The penalties and other sanctions applicable under a law of a State or political subdivision of a State in the event of non-compliance with the identical requirement shall be no more stringent than the penalties and other sanctions available to the Administrator under section 2615 of this title.

**(ii) Penalties**

In the case of an identical requirement—

(I) a State or political subdivision of a State may not assess a penalty for a specific violation for which the Administrator has assessed an adequate penalty under section 2615 of this title; and

(II) if a State or political subdivision of a State has assessed a penalty for a specific violation, the Administrator may not assess a penalty for that violation in an amount that would cause the total of the penalties assessed for the violation by the State or political subdivision of a State and the Administrator combined to exceed the maximum amount that may be assessed for that violation by the Administrator under section 2615 of this title.

**(2) Applicability to certain rules or orders****(A) Prior rules and orders**

Nothing in this section shall be construed as modifying the preemptive effect under this section, as in effect on the day before the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, of any rule or order promulgated or issued under this chapter prior to that effective date.

**(B) Certain chemical substances and mixtures**

With respect to a chemical substance or mixture for which any rule or order was promulgated or issued under section 2605 of this title prior to the effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act with respect to manufacturing, processing, distribution in commerce, use, or disposal of the chemical substance or mixture, nothing in this section shall be construed as modifying the preemptive effect of this section as in effect prior to the enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act of any rule or order that is promulgated or issued with respect to such chemical substance or mixture under section 2605 of this title after that effective date, unless the latter rule or order is with respect to a chemical substance or mixture containing a chemical substance and follows a designation of that chemical substance as a high-priority substance under section 2605(b)(1)(B)(1) of this title, the identification of that chemical substance under section 2605(b)(2)(A) of this title, or the selection of that chemical substance for risk evaluation under section 2605(b)(4)(E)(iv)(II) of this title.

**(e) Preservation of certain laws****(1) In general**

Nothing in this chapter, subject to subsection (g) of this section, shall—

(A) be construed to preempt or otherwise affect the authority of a State or political subdivision of a State to continue to enforce any action taken or requirement imposed or requirement enacted relating to a specific chemical substance before April 22, 2016, under the authority of a law of the State or political subdivision of the State that prohibits or otherwise restricts manufacturing, processing, distribution in commerce, use, or disposal of a chemical substance; or

(B) be construed to preempt or otherwise affect any action taken pursuant to a State law that was in effect on August 31, 2003.

**(2) Effect of subsection**

This subsection does not affect, modify, or alter the relationship between Federal law and laws of a State or political subdivision of a State pursuant to any other Federal law.

**(f) Waivers****(1) Discretionary exemptions**

Upon application of a State or political subdivision of a State, the Administrator may, by rule, exempt from subsection (a), under such conditions as may be prescribed in the rule, a statute, criminal penalty, or administrative action of that State or political subdivision of the State that relates to the effects of exposure to a chemical substance under the conditions of use if the Administrator determines that—

(A) compelling conditions warrant granting the waiver to protect health or the environment;

(B) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(C) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(D) in the judgment of the Administrator, the proposed requirement of the State or political subdivision of the State is designed to address a risk of a chemical substance, under the conditions of use, that was identified—

(i) consistent with the best available science;

(ii) using supporting studies conducted in accordance with sound and objective scientific practices; and

(iii) based on the weight of the scientific evidence.

**(2) Required exemptions**

Upon application of a State or political subdivision of a State, the Administrator shall exempt from subsection (b) a statute or administrative action of a State or political subdivision of a State that relates to the effects of exposure to a chemical substance under the

conditions of use if the Administrator determines that—

(A)(i) compliance with the proposed requirement of the State or political subdivision of the State would not unduly burden interstate commerce in the manufacture, processing, distribution in commerce, or use of a chemical substance;

(ii) compliance with the proposed requirement of the State or political subdivision of the State would not cause a violation of any applicable Federal law, rule, or order; and

(iii) the State or political subdivision of the State has a concern about the chemical substance or use of the chemical substance based in peer-reviewed science; or

(B) no later than the date that is 18 months after the date on which the Administrator has initiated the prioritization process for a chemical substance under the rule promulgated pursuant to section 2605(b)(1)(A) of this title, or the date on which the Administrator publishes the scope of the risk evaluation for a chemical substance under section 2605(b)(4)(D) of this title, whichever is sooner, the State or political subdivision of the State has enacted a statute or proposed or finalized an administrative action intended to prohibit or otherwise restrict the manufacture, processing, distribution in commerce, or use of the chemical substance.

**(3) Determination of a waiver request**

The duty of the Administrator to grant or deny a waiver application shall be nondelegable and shall be exercised—

(A) not later than 180 days after the date on which an application under paragraph (1) is submitted; and

(B) not later than 110 days after the date on which an application under paragraph (2) is submitted.

**(4) Failure to make a determination**

If the Administrator fails to make a determination under paragraph (3)(B) during the 110-day period beginning on the date on which an application under paragraph (2) is submitted, the statute or administrative action of the State or political subdivision of the State that was the subject of the application shall not be considered to be an existing statute or administrative action for purposes of subsection (b) by reason of the failure of the Administrator to make a determination.

**(5) Notice and comment**

Except in the case of an application approved under paragraph (9), the application of a State or political subdivision of a State under this subsection shall be subject to public notice and comment.

**(6) Final agency action**

The decision of the Administrator on the application of a State or political subdivision of a State shall be—

(A) considered to be a final agency action; and

(B) subject to judicial review.

**(7) Duration of waivers**

A waiver granted under paragraph (2) or approved under paragraph (9) shall remain in ef-

fect until such time as the Administrator publishes the risk evaluation under section 2605(b) of this title.

**(8) Judicial review of waivers**

Not later than 60 days after the date on which the Administrator makes a determination on an application of a State or political subdivision of a State under paragraph (1) or (2), any person may file a petition for judicial review in the United States Court of Appeals for the District of Columbia Circuit, which shall have exclusive jurisdiction over the determination.

**(9) Approval**

**(A) Automatic approval**

If the Administrator fails to meet the deadline established under paragraph (3)(B), the application of a State or political subdivision of a State under paragraph (2) shall be automatically approved, effective on the date that is 10 days after the deadline.

**(B) Requirements**

Notwithstanding paragraph (6), approval of a waiver application under subparagraph (A) for failure to meet the deadline under paragraph (3)(B) shall not be considered final agency action or be subject to judicial review or public notice and comment.

**(g) Savings**

**(1) No preemption of common law or statutory causes of action for civil relief or criminal conduct**

**(A) In general**

Nothing in this chapter, nor any amendment made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any standard, rule, requirement, standard of performance, risk evaluation, or scientific assessment implemented pursuant to this chapter, shall be construed to preempt, displace, or supplant any State or Federal common law rights or any State or Federal statute creating a remedy for civil relief, including those for civil damage, or a penalty for a criminal conduct.

**(B) Clarification of no preemption**

Notwithstanding any other provision of this chapter, nothing in this chapter, nor any amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, shall preempt or preclude any cause of action for personal injury, wrongful death, property damage, or other injury based on negligence, strict liability, products liability, failure to warn, or any other legal theory of liability under any State law, maritime law, or Federal common law or statutory theory.

**(2) No effect on private remedies**

**(A) In general**

Nothing in this chapter, nor any amendments made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, nor any rules, regulations, requirements, risk evaluations, scientific assessments, or orders issued pursuant to this chapter shall

be interpreted as, in either the plaintiff's or defendant's favor, dispositive in any civil action.

**(B) Authority of courts**

This chapter does not affect the authority of any court to make a determination in an adjudicatory proceeding under applicable State or Federal law with respect to the admission into evidence or any other use of this chapter or rules, regulations, requirements, standards of performance, risk evaluations, scientific assessments, or orders issued pursuant to this chapter.

(Pub. L. 94-469, title I, §18, Oct. 11, 1976, 90 Stat. 2038; renumbered title I, Pub. L. 99-519, §3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114-182, title I, §13, June 22, 2016, 130 Stat. 492.)

REFERENCES IN TEXT

Section 2605(b)(4)(D) of this title, referred to in subsec. (a)(1)(B)(1), (ii), was in the original "section (6)(b)(4)(D)", and was translated as meaning section 6(b)(4)(D) of title I of Pub. L. 94-469 to reflect the probable intent of Congress.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act, referred to in subsecs. (d)(1)(A), (2) and (g)(1), (2)(A), is Pub. L. 114-182, June 22, 2016, 130 Stat. 492. The effective date of the Frank R. Lautenberg Chemical Safety for the 21st Century Act probably means the date of the enactment of the Act, which was approved June 22, 2016. For complete classification of this Act to the Code, see Short Title of 2016 Amendment note set out under section 2601 of this title and Tables.

AMENDMENTS

2016—Subsec. (a). Pub. L. 114-182, §13(1), amended subsec. (a) generally. Prior to amendment, subsec. (a) related to effect of chapter on State law.

Subsec. (b). Pub. L. 114-182, §13(2), amended subsec. (b) generally. Prior to amendment, subsec. (b) related to exemption from required testing of chemical substances or mixtures.

Subsecs. (c) to (g). Pub. L. 114-182, §13(3), added subsecs. (c) to (g).

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

**§ 2618. Judicial review**

**(a) In general**

(1)(A) Except as otherwise provided in this subchapter, not later than 60 days after the date on which a rule is promulgated under this subchapter, subchapter II, or subchapter IV, or the date on which an order is issued under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,<sup>1</sup> any person may file a petition for judicial review of such rule or order with the United States Court of Appeals for the District of Columbia Circuit or for the circuit in which such person resides or in which such person's principal place of business is located. Courts of appeals of the United States shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of such a rule or order if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(B) Except as otherwise provided in this subchapter, courts of appeals of the United States

shall have exclusive jurisdiction of any action to obtain judicial review (other than in an enforcement proceeding) of an order issued under this subchapter, other than an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, if any district court of the United States would have had jurisdiction of such action but for this subparagraph.

(C)(i) Not later than 60 days after the publication of a designation under section 2605(b)(1)(B)(ii) of this title, any person may commence a civil action to challenge the designation.

(ii) The United States Court of Appeals for the District of Columbia Circuit shall have exclusive jurisdiction over a civil action filed under this subparagraph.

(2) Copies of any petition filed under paragraph (1)(A) shall be transmitted forthwith to the Administrator and to the Attorney General by the clerk of the court with which such petition was filed. The provisions of section 2112 of title 28 shall apply to the filing of the record of proceedings on which the Administrator based the rule or order being reviewed under this section and to the transfer of proceedings between United States courts of appeals.

**(b) Additional submissions and presentations; modifications**

If in an action under this section to review a rule, or an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the petitioner or the Administrator applies to the court for leave to make additional oral submissions or written presentations respecting such rule or order and shows to the satisfaction of the court that such submissions and presentations would be material and that there were reasonable grounds for the submissions and failure to make such submissions and presentations in the proceeding before the Administrator, the court may order the Administrator to provide additional opportunity to make such submissions and presentations. The Administrator may modify or set aside the rule or order being reviewed or make a new rule or order by reason of the additional submissions and presentations and shall file such modified or new rule or order with the return of such submissions and presentations. The court shall thereafter review such new or modified rule or order.

**(c) Standard of review**

(1)(A) Upon the filing of a petition under subsection (a)(1) for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5, and (ii) except as otherwise provided in subparagraph (B), to review such rule or order in accordance with chapter 7 of title 5.

(B) Section 706 of title 5 shall apply to review of a rule or order under this section, except that—

(i) in the case of review of—

(I) a rule under section 2603(a), 2604(b)(4), 2605(a) (including review of the associated determination under section 2605(b)(4)(A)), or 2605(e) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court

<sup>1</sup>So in original.

shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole; and

(II) an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such order if the court finds that the order is not supported by substantial evidence in the record taken as a whole; and

(ii) the court may not review the contents and adequacy of any statement of basis and purpose required by section 553(c) of title 5 to be incorporated in the rule or order, except as part of the record, taken as a whole.

(2) The judgment of the court affirming or setting aside, in whole or in part, any rule or order reviewed in accordance with this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification, as provided in section 1254 of title 28.

**(d) Fees and costs**

The decision of the court in an action commenced under subsection (a), or of the Supreme Court of the United States on review of such a decision, may include an award of costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate.

**(e) Other remedies**

The remedies as provided in this section shall be in addition to and not in lieu of any other remedies provided by law.

(Pub. L. 94-469, title I, § 19, Oct. 11, 1976, 90 Stat. 2039; renumbered title I and amended Pub. L. 99-519, § 3(b)(2), (c)(1), Oct. 22, 1986, 100 Stat. 2989; Pub. L. 102-550, title X, § 1021(b)(8), Oct. 28, 1992, 106 Stat. 3923; Pub. L. 114-182, title I, §§ 14, 19(m), June 22, 2016, 130 Stat. 498, 508.)

**AMENDMENTS**

2016—Subsec. (a)(1)(A). Pub. L. 114-182, § 19(m)(1)(A), substituted “Except as otherwise provided in this subchapter, not later than 60 days after the date on which a rule is promulgated under this subchapter, subchapter II, or subchapter IV, or the date on which an order is issued under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,” for “Not later than 60 days after the date of the promulgation of a rule under section 2603(a), 2604(a)(2), 2604(b)(4), 2605(a), 2605(e), or 2607 of this title, or under subchapter II or IV”, “such rule or order” for “such rule”, and “such a rule or order” for “such a rule”.

Subsec. (a)(1)(B). Pub. L. 114-182, § 19(m)(1)(B), substituted “Except as otherwise provided in this subchapter, courts” for “Courts” and “this subchapter, other than an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,” for “subparagraph (A) or (B) of section 2605(b)(1) of this title”.

Subsec. (a)(1)(C). Pub. L. 114-182, § 14(1), added subpar. (C).

Subsec. (a)(2). Pub. L. 114-182, § 19(m)(1)(C), substituted “record” for “rulemaking record” and “based the rule or order” for “based the rule”.

Subsec. (a)(3). Pub. L. 114-182, § 14(2), struck out par. (3) which defined “rulemaking record”.

Subsec. (b). Pub. L. 114-182, § 19(m)(2), substituted “review a rule, or an order under section 2603, 2604(e), 2604(f), or 2605(i)(1) of this title,” for “review a rule”,

“such rule or order” for “such rule”, “the rule or order” for “the rule”, “new rule or order” for “new rule” in two places, and “modified rule or order” for “modified rule”.

Subsec. (c)(1)(A). Pub. L. 114-182, § 19(m)(3)(A)(i), substituted “a rule or order” for “a rule” and “such rule or order” for “such rule”.

Subsec. (c)(1)(B). Pub. L. 114-182, § 19(m)(3)(A)(ii)(I), substituted “a rule or order” for “a rule” in introductory provisions.

Pub. L. 114-182, § 19(m)(3)(A)(ii)(III), struck out concluding provisions which read as follows: “The term ‘evidence’ as used in clause (i) means any matter in the rulemaking record.”

Subsec. (c)(1)(B)(i). Pub. L. 114-182, § 19(m)(3)(A)(ii)(II), amended cl. (i) generally. Prior to amendment, cl. (i) read as follows: “In the case of review of a rule under section 2603(a), 2604(b)(4), 2605(a), or 2605(e) of this title, the standard for review prescribed by paragraph (2)(E) of such section 706 shall not apply and the court shall hold unlawful and set aside such rule if the court finds that the rule is not supported by substantial evidence in the rulemaking record (as defined in subsection (a)(3)) taken as a whole.”

Subsec. (c)(1)(B)(ii), (iii). Pub. L. 114-182, § 19(m)(3)(A)(ii)(III), added cl. (ii) and struck out former cls. (ii) and (iii) which related to review of rules under section 2605(a) of this title and statements not subject to court review, respectively.

Subsec. (c)(1)(C). Pub. L. 114-182, § 19(m)(3)(A)(iii), struck out subpar. (C) which read as follows: “A determination, rule, or ruling of the Administrator described in subparagraph (B)(ii) may be reviewed only in an action under this section and only in accordance with such subparagraph.”

Subsec. (c)(2). Pub. L. 114-182, § 19(m)(3)(B), substituted “any rule or order” for “any rule”.

1992—Subsec. (a)(1)(A). Pub. L. 102-550, § 1021(b)(8)(A), substituted “subchapter II or IV” for “subchapter II”.

Subsec. (a)(3)(B). Pub. L. 102-550, § 1021(b)(8)(B), inserted before semicolon at end “and in the case of a rule under subchapter IV, the finding required for the issuance of such a rule”.

1986—Subsec. (a)(1)(A). Pub. L. 99-519 inserted reference to subchapter II of this chapter.

**EFFECTIVE DATE**

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94-469, set out as a note under section 2601 of this title.

**§ 2619. Citizens' civil actions**

**(a) In general**

Except as provided in subsection (b), any person may commence a civil action—

(1) against any person (including (A) the United States, and (B) any other governmental instrumentality or agency to the extent permitted by the eleventh amendment to the Constitution) who is alleged to be in violation of this chapter or any rule promulgated under section 2603, 2604, or 2605 of this title, or subchapter II or IV, or order issued under section 2603 or 2604 of this title or subchapter II or IV to restrain such violation, or

(2) against the Administrator to compel the Administrator to perform any act or duty under this chapter which is not discretionary.

Any civil action under paragraph (1) shall be brought in the United States district court for the district in which the alleged violation occurred or in which the defendant resides or in which the defendant's principal place of business is located. Any action brought under paragraph (2) shall be brought in the United States District Court for the District of Columbia, or the

**§ 214. Previous laws unaffected**

Nothing in this chapter shall be construed as modifying or revoking any of the provisions of sections 191 to 193<sup>1</sup> of this title.

(Mar. 3, 1915, ch. 74, § 13, 38 Stat. 822.)

## REFERENCES IN TEXT

Sections 191 to 193 of this title, referred to in text, were repealed by Pub. L. 91-513, title III, § 1101(a)(1), Oct. 27, 1970, 84 Stat. 1291. See section 801 et seq. of this title.

**§ 215. "Consul" defined**

The word "consul" as used in this chapter shall mean the consular officer in charge of the district concerned.

(Mar. 3, 1915, ch. 74, § 12, 38 Stat. 822.)

## CHAPTER 8—NARCOTIC FARMS

 **§§ 221 to 237. Repealed. July 1, 1944, ch. 373, title XIII, § 1313, 58 Stat. 714**

Section 221, act Jan. 19, 1929, ch. 82, § 1, 45 Stat. 1085, defined "habit-forming narcotic drug", "narcotic", and "addict". See section 201 of Title 42, The Public Health and Welfare.

Section 222, act Jan. 19, 1929, ch. 82, § 2, 45 Stat. 1085, provided for narcotic farms.

Section 222a, act June 23, 1935, ch. 725, § 1, 49 Stat. 1840, provided name for narcotic farm at Lexington, Ky.

Section 222b, act Mar. 28, 1938, ch. 55, § 1, 52 Stat. 134, provided name for narcotic farm at Fort Worth, Texas.

Section 223, act Jan. 19, 1929, ch. 82, § 3, 45 Stat. 1085; 1939 Reorg. Plan No. I, § 205(b), eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1425, provided for an annual estimate of expenses of maintenance of narcotic farms.

Section 224, act Jan. 19, 1929, ch. 82, § 4, 45 Stat. 1086, provided for construction of buildings for two of the narcotic farms.

Section 225, acts Jan. 19, 1929, ch. 82, § 5, 45 Stat. 1086; June 14, 1930, ch. 488, § 4(a), 46 Stat. 586; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, provided for control and management of narcotic farms.

Section 226, act Jan. 19, 1929, ch. 82, § 6, 45 Stat. 1086; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for care and treatment of addicts.

Section 227, act Jan. 19, 1929, ch. 82, § 7, 45 Stat. 1086, provided for transfer to and from farms of addicts who are prisoners.

Section 228, act Jan. 19, 1929, ch. 82, § 8, 45 Stat. 1087, provided that it was the duty of prosecuting officers to report convicted persons believed to be addicts.

Section 229, act Jan. 19, 1929, ch. 82, § 9, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for employment of addicts.

Section 230, act Jan. 19, 1929, ch. 82, § 10, 45 Stat. 1087, provided for parole of inmates.

Section 231, act Jan. 19, 1929, ch. 82, § 11, 45 Stat. 1087; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for discharge of addicts.

Section 232, act Jan. 19, 1929, ch. 82, § 12, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for admission of voluntary patients.

Section 233, act Jan. 19, 1929, ch. 82, § 13, 45 Stat. 1088; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R. 2728, 53 Stat. 1424, 1425, provided for furnishing of gratuities and transportation to discharged convicts.

Section 234, act Jan. 19, 1929, ch. 82, § 14, 45 Stat. 1089; 1939 Reorg. Plan No. I, §§ 201, 205, eff. July 1, 1939, 4 F.R.

2728, 53 Stat. 1424, 1425, provided penalties for introduction of narcotic drugs into a narcotic farm.

Section 235, act Jan. 19, 1929, ch. 82, § 15, 45 Stat. 1089, provided penalties for escape of inmates.

Section 236, act Jan. 19, 1929, ch. 82, § 16, 45 Stat. 1089, provided penalties for procuring of escape by inmates.

Section 237, act Jan. 19, 1929, ch. 82, § 17, 45 Stat. 1089, provided for deportation of alien inmates who are entitled to a discharge from narcotic farms.

## RENUMBERING OF REPEALING ACT

Title XIII, § 1313, formerly title VI, § 611, of act July 1, 1944, which repealed these sections, was renumbered title VII, § 711, by act Aug. 13, 1946, ch. 958, § 5, 60 Stat. 1049; § 713, by act Feb. 28, 1948, ch. 83, § 9(b), 62 Stat. 47; title VIII, § 813, by act July 30, 1956, ch. 779, § 3(b), 70 Stat. 721; title IX, § 913, by Pub. L. 88-501, § 4(b), Sept. 4, 1964, 78 Stat. 919; title X, § 1013, by Pub. L. 89-239, § 3(b), Oct. 6, 1965, 79 Stat. 931; title XI, § 1113, by Pub. L. 91-572, § 6(b), Dec. 24, 1970, 84 Stat. 1506; title XII, § 1213, by Pub. L. 92-294, § 3(b), May 16, 1972, 86 Stat. 137; title XIII, § 1313, by Pub. L. 93-154, § 2(b)(2), Nov. 16, 1973, 87 Stat. 604, and was repealed by Pub. L. 93-222, § 7(b), Dec. 29, 1973, 87 Stat. 936.

## CHAPTER 9—FEDERAL FOOD, DRUG, AND COSMETIC ACT

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<sup>1</sup> See References in Text note below.

into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

(June 25, 1938, ch. 675, § 406, 52 Stat. 1049; Pub. L. 85-929, § 3(c), Sept. 6, 1958, 72 Stat. 1785; Pub. L. 86-618, title I, § 103(a)(1), July 12, 1960, 74 Stat. 398.)

## AMENDMENTS

1960—Pub. L. 86-618 repealed subsec. (b) which required Secretary to promulgate regulations for listing of coal-tar colors.

1958—Subsec. (a). Pub. L. 85-929 substituted "clause (2)(A)" for "clause (2)" in first sentence.

## EFFECTIVE DATE OF 1960 AMENDMENT

Amendment by Pub. L. 86-618 effective July 12, 1960, subject to the provisions of section 203 of Pub. L. 86-618, see section 202 of Pub. L. 86-618, set out as a note under section 379e of this title.

## EFFECTIVE DATE OF NEMATOCIDE, PLANT REGULATOR, DEFOLIANT, AND DESICCANT AMENDMENT OF 1959

Effective date of subsec. (a) as in force prior to July 22, 1954, with respect to particular commercial use of a nematocide, plant regulator, defoliant, or desiccant in or on a raw agricultural commodity made before Jan. 1, 1958, see section 9(b) of Pub. L. 86-139, Aug. 7, 1959, 73 Stat. 288.

## EFFECTIVE DATE OF 1958 AMENDMENT

For effective date of amendment by Pub. L. 85-929, see section 6(b), (c) of Pub. L. 85-929, set out as a note under section 342 of this title.

## TRANSFER OF FUNCTIONS

Functions vested in Secretary of Health, Education, and Welfare [now Health and Human Services] in establishing tolerances for pesticide chemicals under this section together with authority to monitor compliance with tolerances and effectiveness of surveillance and enforcement and to provide technical assistance to States and conduct research under this chapter and section 201 et seq. of Title 42, The Public Health and Welfare, transferred to Administrator of Environmental Protection Agency by Reorg. Plan No. 3 of 1970, § 2(a)(4), eff. Dec. 2, 1970, 35 F.R. 15623, 84 Stat. 2086, set out in the Appendix to Title 5, Government Organization and Employees.

For transfer of functions of Federal Security Administrator to Secretary of Health, Education, and Welfare [now Health and Human Services], and of Food and Drug Administration to Federal Security Agency, see notes set out under section 321 of this title.

## § 346a. Tolerances and exemptions for pesticide chemical residues

## (a) Requirement for tolerance or exemption

## (1) General rule

Except as provided in paragraph (2) or (3), any pesticide chemical residue in or on a food shall be deemed unsafe for the purpose of section 342(a)(2)(B) of this title unless—

(A) a tolerance for such pesticide chemical residue in or on such food is in effect under this section and the quantity of the residue is within the limits of the tolerance; or

(B) an exemption from the requirement of a tolerance is in effect under this section for the pesticide chemical residue.

For the purposes of this section, the term "food", when used as a noun without modifica-

tion, shall mean a raw agricultural commodity or processed food.

## (2) Processed food

Notwithstanding paragraph (1)—

(A) if a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance for the pesticide chemical residue in or on the processed food if the pesticide chemical has been used in or on the raw agricultural commodity in conformity with a tolerance under this section, such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice, and the concentration of the pesticide chemical residue in the processed food is not greater than the tolerance prescribed for the pesticide chemical residue in the raw agricultural commodity; or

(B) if an exemption for the requirement for a tolerance is in effect under this section for a pesticide chemical residue in or on a raw agricultural commodity, a pesticide chemical residue that is present in or on a processed food because the food is made from that raw agricultural commodity shall not be considered unsafe within the meaning of section 342(a)(2)(B) of this title.

## (3) Residues of degradation products

If a pesticide chemical residue is present in or on a food because it is a metabolite or other degradation product of a precursor substance that itself is a pesticide chemical or pesticide chemical residue, such a residue shall not be considered to be unsafe within the meaning of section 342(a)(2)(B) of this title despite the lack of a tolerance or exemption from the need for a tolerance for such residue in or on such food if—

(A) the Administrator has not determined that the degradation product is likely to pose any potential health risk from dietary exposure that is of a different type than, or of a greater significance than, any risk posed by dietary exposure to the precursor substance;

(B) either—

(i) a tolerance is in effect under this section for residues of the precursor substance in or on the food, and the combined level of residues of the degradation product and the precursor substance in or on the food is at or below the stoichiometrically equivalent level that would be permitted by the tolerance if the residue consisted only of the precursor substance rather than the degradation product; or

(ii) an exemption from the need for a tolerance is in effect under this section for residues of the precursor substance in or on the food; and

(C) the tolerance or exemption for residues of the precursor substance does not state

that it applies only to particular named substances and does not state that it does not apply to residues of the degradation product.

**(4) Effect of tolerance or exemption**

While a tolerance or exemption from the requirement for a tolerance is in effect under this section for a pesticide chemical residue with respect to any food, the food shall not by reason of bearing or containing any amount of such a residue be considered to be adulterated within the meaning of section 342(a)(1) of this title.

**(b) Authority and standard for tolerance**

**(1) Authority**

The Administrator may issue regulations establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's own initiative under subsection (e).

As used in this section, the term "modify" shall not mean expanding the tolerance to cover additional foods.

**(2) Standard**

**(A) General rule**

**(i) Standard**

The Administrator may establish or leave in effect a tolerance for a pesticide chemical residue in or on a food only if the Administrator determines that the tolerance is safe. The Administrator shall modify or revoke a tolerance if the Administrator determines it is not safe.

**(ii) Determination of safety**

As used in this section, the term "safe", with respect to a tolerance for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

**(iii) Rule of construction**

With respect to a tolerance, a pesticide chemical residue meeting the standard under clause (1) is not an eligible pesticide chemical residue for purposes of subparagraph (B).

**(B) Tolerances for eligible pesticide chemical residues**

**(i) Definition**

As used in this subparagraph, the term "eligible pesticide chemical residue" means a pesticide chemical residue as to which—

(I) the Administrator is not able to identify a level of exposure to the residue at which the residue will not cause or contribute to a known or anticipated harm to human health (referred to in this section as a "nonthreshold effect");

(II) the lifetime risk of experiencing the nonthreshold effect is appropriately

assessed by quantitative risk assessment; and

(III) with regard to any known or anticipated harm to human health for which the Administrator is able to identify a level at which the residue will not cause such harm (referred to in this section as a "threshold effect"), the Administrator determines that the level of aggregate exposure is safe.

**(ii) Determination of tolerance**

Notwithstanding subparagraph (A)(1), a tolerance for an eligible pesticide chemical residue may be left in effect or modified under this subparagraph if—

(I) at least one of the conditions described in clause (iii) is met; and

(II) both of the conditions described in clause (iv) are met.

**(iii) Conditions regarding use**

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) Use of the pesticide chemical that produces the residue protects consumers from adverse effects on health that would pose a greater risk than the dietary risk from the residue.

(II) Use of the pesticide chemical that produces the residue is necessary to avoid a significant disruption in domestic production of an adequate, wholesome, and economical food supply.

**(iv) Conditions regarding risk**

For purposes of clause (ii), the conditions described in this clause with respect to a tolerance for an eligible pesticide chemical residue are the following:

(I) The yearly risk associated with the nonthreshold effect from aggregate exposure to the residue does not exceed 10 times the yearly risk that would be allowed under subparagraph (A) for such effect.

(II) The tolerance is limited so as to ensure that the risk over a lifetime associated with the nonthreshold effect from aggregate exposure to the residue is not greater than twice the lifetime risk that would be allowed under subparagraph (A) for such effect.

**(v) Review**

Five years after the date on which the Administrator makes a determination to leave in effect or modify a tolerance under this subparagraph, and thereafter as the Administrator deems appropriate, the Administrator shall determine, after notice and opportunity for comment, whether it has been demonstrated to the Administrator that a condition described in clause (iii)(I) or clause (iii)(II) continues to exist with respect to the tolerance and that the yearly and lifetime risks from aggregate exposure to such residue continue to comply with the limits specified in clause (iv). If the Administrator determines by such

date that such demonstration has not been made, the Administrator shall, not later than 180 days after the date of such determination, issue a regulation under subsection (e)(1) to modify or revoke the tolerance.

**(vi) Infants and children**

Any tolerance under this subparagraph shall meet the requirements of subparagraph (C).

**(C) Exposure of infants and children**

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption for a pesticide chemical residue, the Administrator—

(i) shall assess the risk of the pesticide chemical residue based on—

(I) available information about consumption patterns among infants and children that are likely to result in disproportionately high consumption of foods containing or bearing such residue among infants and children in comparison to the general population;

(II) available information concerning the special susceptibility of infants and children to the pesticide chemical residues, including neurological differences between infants and children and adults, and effects of in utero exposure to pesticide chemicals; and

(III) available information concerning the cumulative effects on infants and children of such residues and other substances that have a common mechanism of toxicity; and

(ii) shall—

(I) ensure that there is a reasonable certainty that no harm will result to infants and children from aggregate exposure to the pesticide chemical residue; and

(II) publish a specific determination regarding the safety of the pesticide chemical residue for infants and children.

The Secretary of Health and Human Services and the Secretary of Agriculture, in consultation with the Administrator, shall conduct surveys to document dietary exposure to pesticides among infants and children. In the case of threshold effects, for purposes of clause (ii)(I) an additional tenfold margin of safety for the pesticide chemical residue and other sources of exposure shall be applied for infants and children to take into account potential pre- and post-natal toxicity and completeness of the data with respect to exposure and toxicity to infants and children. Notwithstanding such requirement for an additional margin of safety, the Administrator may use a different margin of safety for the pesticide chemical residue only if, on the basis of reliable data, such margin will be safe for infants and children.

**(D) Factors**

In establishing, modifying, leaving in effect, or revoking a tolerance or exemption

for a pesticide chemical residue, the Administrator shall consider, among other relevant factors—

(i) the validity, completeness, and reliability of the available data from studies of the pesticide chemical and pesticide chemical residue;

(ii) the nature of any toxic effect shown to be caused by the pesticide chemical or pesticide chemical residue in such studies;

(iii) available information concerning the relationship of the results of such studies to human risk;

(iv) available information concerning the dietary consumption patterns of consumers (and major identifiable subgroups of consumers);

(v) available information concerning the cumulative effects of such residues and other substances that have a common mechanism of toxicity;

(vi) available information concerning the aggregate exposure levels of consumers (and major identifiable subgroups of consumers) to the pesticide chemical residue and to other related substances, including dietary exposure under the tolerance and all other tolerances in effect for the pesticide chemical residue, and exposure from other non-occupational sources;

(vii) available information concerning the variability of the sensitivities of major identifiable subgroups of consumers;

(viii) such information as the Administrator may require on whether the pesticide chemical may have an effect in humans that is similar to an effect produced by a naturally occurring estrogen or other endocrine effects; and

(ix) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

**(E) Data and information regarding anticipated and actual residue levels**

**(i) Authority**

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may consider available data and information on the anticipated residue levels of the pesticide chemical in or on food and the actual residue levels of the pesticide chemical that have been measured in food, including residue data collected by the Food and Drug Administration.

**(ii) Requirement**

If the Administrator relies on anticipated or actual residue levels in establishing, modifying, or leaving in effect a tolerance, the Administrator shall pursuant to subsection (f)(1) require that data be provided five years after the date on which the tolerance is established, modified, or left in effect, and thereafter as the Administrator deems appropriate, demonstrating that such residue levels are not above the

levels so relied on. If such data are not so provided, or if the data do not demonstrate that the residue levels are not above the levels so relied on, the Administrator shall, not later than 180 days after the date on which the data were required to be provided, issue a regulation under subsection (e)(1), or an order under subsection (f)(2), as appropriate, to modify or revoke the tolerance.

**(F) Percent of food actually treated**

In establishing, modifying, leaving in effect, or revoking a tolerance for a pesticide chemical residue, the Administrator may, when assessing chronic dietary risk, consider available data and information on the percent of food actually treated with the pesticide chemical (including aggregate pesticide use data collected by the Department of Agriculture) only if the Administrator—

(i) finds that the data are reliable and provide a valid basis to show what percentage of the food derived from such crop is likely to contain such pesticide chemical residue;

(ii) finds that the exposure estimate does not understate exposure for any significant subpopulation group;

(iii) finds that, if data are available on pesticide use and consumption of food in a particular area, the population in such area is not dietarily exposed to residues above those estimated by the Administrator; and

(iv) provides for the periodic reevaluation of the estimate of anticipated dietary exposure.

**(3) Detection methods**

**(A) General rule**

A tolerance for a pesticide chemical residue in or on a food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary, that there is a practical method for detecting and measuring the levels of the pesticide chemical residue in or on the food.

**(B) Detection limit**

A tolerance for a pesticide chemical residue in or on a food shall not be established at or modified to a level lower than the limit of detection of the method for detecting and measuring the pesticide chemical residue specified by the Administrator under subparagraph (A).

**(4) International standards**

In establishing a tolerance for a pesticide chemical residue in or on a food, the Administrator shall determine whether a maximum residue level for the pesticide chemical has been established by the Codex Alimentarius Commission. If a Codex maximum residue level has been established for the pesticide chemical and the Administrator does not propose to adopt the Codex level, the Administrator shall publish for public comment a notice explaining the reasons for departing from the Codex level.

**(c) Authority and standard for exemptions**

**(1) Authority**

The Administrator may issue a regulation establishing, modifying, or revoking an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food—

(A) in response to a petition filed under subsection (d); or

(B) on the Administrator's initiative under subsection (e).

**(2) Standard**

**(A) General rule**

**(i) Standard**

The Administrator may establish or leave in effect an exemption from the requirement for a tolerance for a pesticide chemical residue in or on food only if the Administrator determines that the exemption is safe. The Administrator shall modify or revoke an exemption if the Administrator determines it is not safe.

**(ii) Determination of safety**

The term "safe", with respect to an exemption for a pesticide chemical residue, means that the Administrator has determined that there is a reasonable certainty that no harm will result from aggregate exposure to the pesticide chemical residue, including all anticipated dietary exposures and all other exposures for which there is reliable information.

**(B) Factors**

In making a determination under this paragraph, the Administrator shall take into account, among other relevant considerations, the considerations set forth in subparagraphs (C) and (D) of subsection (b)(2).

**(3) Limitation**

An exemption from the requirement for a tolerance for a pesticide chemical residue in or on food shall not be established or modified by the Administrator unless the Administrator determines, after consultation with the Secretary—

(A) that there is a practical method for detecting and measuring the levels of such pesticide chemical residue in or on food; or

(B) that there is no need for such a method, and states the reasons for such determination in issuing the regulation establishing or modifying the exemption.

**(d) Petition for tolerance or exemption**

**(1) Petitions and petitioners**

Any person may file with the Administrator a petition proposing the issuance of a regulation—

(A) establishing, modifying, or revoking a tolerance for a pesticide chemical residue in or on a food; or

(B) establishing, modifying, or revoking an exemption from the requirement of a tolerance for such a residue.

**(2) Petition contents**

**(A) Establishment**

A petition under paragraph (1) to establish a tolerance or exemption for a pesticide

the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes. Thus, Executive Order 13175 does not apply to this action.

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

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2-202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not a "significant energy action" as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on the supply, distribution or use of energy. This rulemaking addresses internal EPA operations and procedures and does not impose any requirements on the public.

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

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

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

This action does not establish an environmental health or safety standard, and is therefore not subject to environmental justice considerations under Executive Order 12898 (59 FR 7629, February 16, 1994). This rulemaking addresses internal EPA operations and procedures and does not have any impact on human health or the environment.

**VII. Congressional Review Act (CRA)**

This rule is exempt from the CRA, 5 U.S.C. 801 *et seq.*, because it is a rule of agency organization, procedure or practice that does not substantially affect the rights or obligations of non-agency parties.

**List of Subjects in 40 CFR Part 702**

Environmental protection, Chemical substances, Chemicals, Hazardous substances, Health and safety, Prioritization, Screening, Toxic substances.

Dated: June 22, 2017.

**E. Scott Pruitt,**  
Administrator.

Therefore, 40 CFR chapter I, subchapter R, is amended as follows:

**PART 702—GENERAL PRACTICES AND PROCEDURES**

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

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

- 2. Add subpart A to read as follows:

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

Sec.

- 702.1 General provisions.
- 702.3 Definitions.
- 702.4 [Reserved]
- 702.5 Candidate selection.
- 702.7 Initiation of prioritization process.
- 702.9 Screening review and proposed priority designation.
- 702.11 Final priority designation.
- 702.13 Revision of designation.
- 702.15 Effect of designation as a low-priority substance.
- 702.17 Effect of designation as a high-priority substance.

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

**§ 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.

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**Subpart B—Procedures for Chemical Substance Risk Evaluations****Sec.**

- 702.31 General provisions.  
 702.33 Definitions.  
 702.35 Chemical substances designated for risk evaluation.  
 702.37 Submission of manufacturer requests for risk evaluations.  
 702.39 Interagency collaboration.  
 702.41 Evaluation requirements.  
 702.43 Risk Characterization.  
 702.45 Peer review.  
 702.47 Unreasonable risk determination.  
 702.49 Risk evaluation timeframes and actions.  
 702.51 Publicly available information.

**§ 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's 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 moot 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).

#### § 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 Publicly 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.

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## ENVIRONMENTAL PROTECTION AGENCY

### 40 CFR Part 702

[EPA-HQ-OPPT-2016-0636; FRL-9964-24]

RIN 2070-AK23

#### Procedures for Prioritization of Chemicals for Risk Evaluation Under the Toxic Substances Control Act

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

**SUMMARY:** As required under section 6(b)(1) of the Toxic Substances Control Act (TSCA), EPA is issuing a final rule that establishes the process and criteria that EPA will use to identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time. The final rule describes the processes for formally initiating the prioritization process on a selected candidate, providing opportunities for public comment, screening the candidate against certain criteria, and proposing and finalizing designations of priority. Prioritization is the initial step in a new process of existing chemical substance review and risk management activity established under TSCA.

**DATES:** This final rule is effective September 18, 2017.

**ADDRESSES:** The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0636, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC 20460-0001. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://www.epa.gov/dockets>.

#### FOR FURTHER INFORMATION CONTACT:

For technical information contact: Susanna W. Blair, Immediate Office, Office of Pollution Prevention and

Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW., Washington, DC 20460-0001; telephone number: (202) 564-4321; email address: [blair.susanna@epa.gov](mailto:blair.susanna@epa.gov).

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: [TSCA-Hotline@epa.gov](mailto:TSCA-Hotline@epa.gov).

#### SUPPLEMENTARY INFORMATION:

##### I. Executive Summary

###### A. What action is the Agency taking?

EPA is promulgating this final rule to establish the process and criteria by which EPA will identify chemical substances as either High-Priority Substances for risk evaluation, or Low-Priority Substances for which risk evaluations are not warranted at the time.

###### B. Does this action apply to me?

This final rule does not establish any requirements on persons or entities outside of the Agency. This action may, however, be of interest to entities that are manufacturing or may manufacture or import a chemical substance regulated under TSCA (e.g., entities identified under North American Industrial Classification System (NAICS) codes 325 and 324110). Since other entities may also be interested, the Agency has not attempted to describe all the specific entities and corresponding NAICS codes for entities that may be interested in or affected by this action.

###### C. Why is the Agency taking this action?

This rulemaking is required by TSCA section 6(b)(1)(A), 15 U.S.C. 2605(b)(1)(A). Prioritization of chemical substances for further evaluation will help to ensure that the Agency's limited resources are conserved for those chemical substances most likely to present risks, thereby furthering EPA's overall mission to protect health and the environment.

###### D. What is the Agency's authority for taking this action?

This final rule is issued pursuant to the authority in TSCA section 6(b), 15 U.S.C. 2605(b).

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

This final rule establishes the processes by which EPA intends to designate chemical substances as either High or Low-Priority Substances for risk evaluation. It does not establish any requirements on persons or entities outside of the Agency. No incremental