No. 19-1042 (L)

19-1044(con), 19-2329 (con)

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT; NATURAL RESOURCES DEFENSE COUNCIL, INC.; VERMONT PUBLIC INTEREST RESEARCH GROUP; SAFER CHEMICALS HEALTHY FAMILIES; LAUREN ATKINS; WENDY HARTLEY; AND HALOGENATED SOLVENTS INDUSTRY ALLIANCE, INC.,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY and ANDREW R. WHEELER, as Administrator of the United States Environmental Protection Agency,

Respondents.

On Petition for Review of a Rule of the
United States Environmental Protection Agency

PAGE-PROOF RESPONSE BRIEF FOR U.S. ENVIRONMENTAL PROTECTION AGENCY AND ANDREW R. WHEELER

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INTRODUCTION

Petitioners challenge here the first final action of a multistep administrative process by EPA regarding methylene chloride under the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2625(*l*)(4). Methylene chloride is a solvent commonly used in paint and coating removal products that have been widely available to both consumer and commercial users through home improvement stores and internet vendors, among others.

In the rule challenged here, EPA found that when consumers used methylene chloride for paint and coating removal in settings such as homes, workshops, and garages, the chemical substance can cause neurological impacts such as dizziness, incapacitation, loss of consciousness, coma, and death. EPA determined that this risk from the use of methylene chloride in consumer paint and coating removal is unreasonable. EPA promulgated regulations prohibiting the manufacture (including import), processing, or distribution of methylene chloride for consumer paint and coating removal, among other restrictions not at issue here. *See* Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 84 Fed. Reg. 11,420 (Mar. 27, 2019) ("Final Rule").

Two sets of petitioners have petitioned for review of this rule. Labor Council for Latin American Advancement et al. and Vermont Public Interest Research Group et al. (hereinafter, "Environmental Petitioners"), contend that the rule does not go far enough. According to Environmental Petitioners, EPA erred by not also prohibiting

the use and distribution of methylene chloride for commercial paint and coating removal. EPA had proposed to adopt such restrictions in its Notice of Proposed Rulemaking. Methylene Chloride and N-Methylpyrrolidone; Regulation of Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7464, 7464 (Jan. 19, 2017), JA__ ("Proposed Rule"). But EPA did not finalize that restriction in the Final Rule. Instead, EPA has stated it is continuing weigh comments and evidence regarding commercial uses. EPA will address commercial use in a second, later, rulemaking.

Halogenated Solvents Industry Alliance, Inc. ("HSIA"), on the other hand, contends that EPA's first rulemaking went too far. HSIA argues that EPA did not provide adequate notice of the way that the consumer distribution prohibition would be executed—via a ban on sales by and to retailers—and did not adequately account for the Final Rule's impact on industry. But EPA's Final Rule is a logical outgrowth of the proposed consumer distribution ban. Further, HSIA seeks to give greater weight to cost considerations than Congress specified in TSCA.

Importantly, HSIA does not challenge EPA's determination that the acute lethal risk presented by methylene chloride use in consumer paint and coating removal is unreasonable. In light of that determination, TSCA authorizes EPA to promulgate a rule imposing requirements to the extent necessary to ensure that risk is "no longer present[ed]." 15 U.S.C. § 2605(a). That is precisely what EPA did. EPA's conclusion that it was necessary to prohibit distribution in commerce of methylene chloride-

containing paint and coating removers for consumer use by banning sales by retailers to address the unreasonable risk is well-supported.

And although Environmental Petitioners would have preferred EPA to finalize a prohibition on the use of methylene chloride in commercial paint and coating removal, EPA was not required to do so. Instead, the administrative process to address that activity is ongoing. This Court accordingly should defer review of any action on commercial paint and coating removal until EPA has completed it. TSCA did not require EPA to finalize a determination regarding commercial paint and coating removal at this time. EPA reasonably deferred its action to solicit further comment and conduct further analysis of this activity. The Court should deny all the petitions.

STATEMENT OF JURISDICTION

The Court's jurisdiction arises under the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2618(a)(1)(A). EPA's final rule regarding consumer uses of methylene chloride for paint and coating removal, Methylene Chloride: Regulation of Paint and Coating Removal for Consumer Use under TSCA Section 6(a), 84 Fed. Reg. 11,420 (Mar. 27, 2019), was promulgated under 15 U.S.C. §§ 2625(*l*)(4) and 2605(a). The three petitions for review before the court—two by Labor Council for Latin American Advancement, *et al.*, and Vermont Public Interest Group, *et al* (collectively, "Environmental Petitioners), and one by Halogenated Solvents Industry Alliance ("Industry Petitioner")—were timely filed and then consolidated in the Second

Circuit. As explained in section I.A. of the argument, however, Environmental Petitioners' claims challenge non-final action and therefore are not reviewable.

STATEMENT OF THE ISSUES

1. Can the Court review EPA's non-final action on commercial use of methylene chloride paint and coating removers where the Agency had no statutory duty to complete the action at this time, has not made a final risk determination, and continues to consider regulatory options for addressing potential unreasonable risk?

2. Is EPA's inaction on commercial paint and coating removal ripe for review where it is actively engaged in an administrative process that will imminently lead to a determination that will more concretely set up the issue for review?

3. Was EPA required to promulgate a rule addressing the use of methylene chloride in commercial paint and coating removal where EPA's authority under § 2625(*l*)(4) is discretionary and it has not determined, pursuant to a risk evaluation under § 2605(b)(4), whether that use presents unreasonable risk?

4. If reviewable, did EPA reasonably decide to defer regulation of commercial use of methylene chloride until it could collect more information?

5. Was the Final Rule's ban on retail distribution a logical outgrowth of EPA's stated goal in the proposed rule to prevent consumers from accessing such products?

6. Did EPA reasonably assess the "reasonably ascertainable" relative costs of the Final Rule's retailer ban against the primary regulatory alternative, a 55-gallon volume restriction, and "factor in" those costs consistent with 15 U.S.C. § 2605(c)(2)(B)?

7. Was the Final Rule, which no party disputes addresses the unreasonable risk presented by methylene chloride use in consumer paint and coating removal, supported by substantial evidence, including a reasonable assessment of economic costs?

STATEMENT OF THE CASE

This case arises out of EPA's final action addressing the unreasonable risk of injury to health presented by the use of methylene chloride for consumer paint and coating removal. In that Final Rule, EPA did not finalize a risk determination or any associated risk management action for commercial paint and coating removal. Such a determination and potential action remains under review. Environmental Petitioners contend EPA arbitrarily or capriciously declined to address commercial use of methylene chloride in paint and coating removers. HSIA contends EPA arbitrarily or capriciously prohibited the distribution for consumer use by banning distribution through retailers. These petitions should both be denied.

A. Statutory Background

Congress enacted TSCA in 1976 "to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances." S. Rep. No. 94-698, at 1 (1976), *as reprinted in* 1976 U.S.C.C.A.N. 4491. In particular, Congress established a policy under which "adequate authority should exist to regulate chemical substances and mixtures which present an unreasonable risk of injury to health or the environment[.]" 15 U.S.C. § 2601(b)(2). Congress expressed that the primary purpose of the Act is to "assure that [technological] innovation and commerce in . . . chemical substances and mixtures do not present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2601(b)(3).

Before 2016, TSCA authorized EPA to regulate chemical substances if the Agency found there was a "reasonable basis" to conclude that their manufacture, processing, distribution, use, or disposal "presents or will present an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a) (1976). Determining whether a chemical presented an "unreasonable risk" was the result of cost-benefit balancing, and EPA was required to use the "least burdensome requirements" to address any identified unreasonable risk. *See Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215 (5th Cir. 1991). Additionally, as originally enacted, TSCA did not provide a specific process or timeline by which EPA was required to assess and manage a chemical substance's unreasonable risks.

In 2016, Congress enacted the Frank R. Lautenberg Chemical Safety for the 21st Century Act, amending TSCA. Pub. L. No. 114-182 (June 22, 2016). The 2016 TSCA amendments "set[] in motion a process under which EPA will for the first time systematically review the safety of chemicals in active commerce." 162 Cong. Rec. at S3516 col. 3 (June 7, 2016).

In the 2016 TSCA amendments, Congress created a three-step triage process. This requires EPA to assess existing chemicals most likely to pose risks and issue regulations to mitigate unreasonable risks. Each of the steps is subject to statutory deadlines. *See* 15 U.S.C. § 2605(b)(4)(D), (G), (c)(1). In general, EPA first "prioritizes" individual chemicals as either low- or high-priority and then conducts "risk

evaluations" of high priority chemicals. *Id.* § 2605(b)(1), (2)(A)–(C).[1] In a risk evaluation, EPA determines "whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, . . . under the conditions of use." *Id.* § 2605(b)(4)(A). An order finding "no unreasonable risk," under relevant conditions of use, is a final action and is subject to judicial review. *Id.* §§ 2605(i)(1), 2618(a)(1)(A); *see* 40 C.F.R. § 702.47.

In the final step, for a chemical found to pose an unreasonable risk under any of its conditions of use, EPA must propose a risk management rule within a year, and must finalize that rule within two years. *Id.* § 2605(a)(1), (c)(1).[2] A risk management rule must impose requirements to the extent necessary to remove the unreasonable risk presented by the chemical substance under the particular condition of use. *Id.* § 2605(a). Potential requirements EPA may impose are drawn from a menu of options in Section 2605(a). These include "prohibiting or otherwise restricting the manufacturing, processing, or distribution in commerce" of a particular chemical

[1] For the first round of risk evaluations, Congress required EPA to select 10 chemicals from the 2014 update to the TSCA Work Plan, a list of chemicals EPA had identified for assessment based on their potential for exposure and hazard under pre-amendment TSCA, without undertaking prioritization of those substances. 15 U.S.C. § 2605(b)(2)(A); TSCA Work Plan (2014 Update) at 2–3, JA__. Manufacturers may also request EPA undertake risk evaluation of a chemical. 15 U.S.C. § 2605(b)(4)(C)(ii).

[2] In many cases, EPA may extend that deadline up to an additional two years. 15 U.S.C. § 2605(c)(1).

substance and "prohibiting or otherwise regulating any manner or method of commercial use of such substance or mixture . . . ." *Id.* § 2605(a)(1), (a)(5).

In proposing and promulgating a rule under Section 2605(a), EPA must consider and publish a statement with respect to various factors, including the chemical substance's effects on health and the environment, its benefits for various uses, and the "reasonably ascertainable economic consequences of the rule." *Id.* § 2605(c)(2)(A)(iv). This consideration of economic consequences includes "the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator." *Id.* § 2605(c)(2)(A)(iv)(II). TSCA directed EPA to "factor in, to the extent possible," those considerations when "selecting among prohibitions and other restrictions." *Id.* § 2605(c)(2)(B). EPA is to make decisions based on a weight of the scientific evidence standard. *Id.* § 2625(i). A risk management rule, including the preceding unreasonable risk determination, is a final action subject to judicial review. *Id.* §§ 2605(i)(2), 2618(a)(1)(A).

Apart from this process, and other processes described *infra* note 13 for a narrow set of chemical substances, the TSCA amendments provide EPA authority to promulgate risk management rules outside of the new three-stage prioritization, risk evaluation, and risk management process—including the deadlines described above. In particular, for certain chemicals included in the 2014 TSCA Work Plan for which

EPA had already published a completed risk assessment[3] prior to the 2016 amendments, Congress granted EPA broad discretion to "publish proposed and final rules under [§ 2605(a)] that are consistent with the scope of the completed risk assessment . . . and consistent with other applicable requirements of section 6." 15 U.S.C. § 2625(*l*)(4). But Congress neither required EPA to act under this section nor prescribed a deadline should EPA choose to exercise this authority. EPA promulgated the Final Rule at issue under Section 2625(*l*)(4).

B. Administrative Background

Methylene chloride is a volatile organic compound used as a solvent in a wide range of industrial, commercial, and consumer use applications, including many paint removal products. MeCl Risk Assessment at 28, JA__. EPA identified methylene chloride in the 2012 TSCA Work Plan for Chemical Assessments and it remained listed after the 2014 update to that Work Plan. TSCA Work Plan at 18, JA__. Consistent with this Work Plan, in 2014, EPA published a risk assessment of methylene chloride in paint removers and strippers in both commercial and consumer settings. 2014 Risk Assessment, JA__. The Risk Assessment identified a number of cancer and non-cancer risks from use of methylene chloride-containing paint strippers. 2014 Risk Assessment, JA__. Risks of acute exposure included "death,

[3] Notably, "risk assessment" and "risk evaluation" are distinct terms of art, as explained further *infra* Part I.C.2. Environmental Petitioners' description of this distinction, Environmental Petitioners' Br. ("EP Br.") at 6 n.1, is incomplete.

neurological impacts such as coma, incapacitation, loss of consciousness and liver effects." 82 Fed. Reg. at 7471. Risks of chronic exposure included "brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple myeloma." *Id.* at 7468.

Although recognizing these risks, the 2014 Risk Assessment was a scientific document. At no point did it purport to make a policy-based determination that the identified risks were "unreasonable risks" under 15 U.S.C. § 2605(a). *See* 2014 Risk Assessment at 119–20, JA__. In this way, the Risk Assessment is different from a "risk evaluation" under Section 2605(b). In a risk evaluation, EPA makes a risk-based policy determination whether a chemical substance presents an "unreasonable risk" within the meaning of Section 2605(b)(4)(A). EPA did not propose a determination of "unreasonable risk" until its 2017 Proposed Rule.

Environmental Petitioners frequently refer to an EPA determination in the 2014 Risk Assessment that certain uses pose "unreasonable risks." See, e.g., EP Br. at 13 & n.3. Again, the Risk Assessment made no legal or policy determination about "unreasonable risks" within the meaning of Section 2605. And, even if the Risk Assessment had included a determination of unreasonable risk, the determination would have been made under pre-amendment TSCA's cost-benefit standard. *See* 15 U.S.C. § 2605(a) (1976).

1. 2017 Proposed Rule

Based on the 2014 Risk Assessment, in January 2017, EPA exercised its Section 26(*l*)(4) discretionary authority to propose a Section 2605(a) rule regarding commercial

and consumer uses of methylene chloride in paint and coating removal. First, EPA proposed to determine that methylene chloride posed an unreasonable risk of injury to health in both commercial and consumer paint and coating removal uses. 82 Fed. Reg. at 7464.[4]

Second, EPA proposed risk management requirements under Section 2605(a). EPA proposed to prohibit "the manufacture (including import), processing, and distribution in commerce of methylene chloride for all consumer and for most types of commercial paint and coating removal uses," and to require certain downstream notification and recordkeeping requirements. 82 Fed. Reg. at 7488. EPA also proposed to prohibit the use of methylene chloride for most types of commercial paint and coating removal.[5]

EPA received tens of thousands of comments, most from mass-mailing campaigns, in response to the Proposed Rule. See 84 Fed. Reg. at 11,424; Response to Comments, JA__. The vast majority of comments supported the proposed rule and

[4] Commercial paint and coating removal is that "performed by an individual, government entity, or company" for which that person "receives remuneration or other form of payment." 82 Fed. Reg. at 7492–93. Consumer paint and coating removal is that "performed by any natural person who uses a paint and coating removal product for any personal use without receiving remuneration or other form of payment." 40 C.F.R. § 751.103.

[5] The Proposed Rule did not address all commercial uses of methylene chloride in paint and coating removal. For example, while EPA proposed to find that use of methylene chloride in commercial furniture refinishing presented unreasonable risk, it did not propose risk management restrictions for that use. 84 Fed. Reg. at 7465.

EPA's proposed determination that the use of methylene chloride in both consumer and commercial paint and coating removal posed an unreasonable risk of injury to human health. *See* Response to Comments at 7–8, JA__.

EPA also received comments advocating for a different regulatory approach to managing risk presented by commercial use. For example, prior to publishing the Proposed Rule, the Small Business Advocacy Review Panel recommended that EPA consider an alternative approach to a ban. It suggested a certification program "with increased training and education" for commercial users. SBAR Report Executive Summary, Sept. 26, 2016, at 5–6, JA__. The Department of Defense similarly urged EPA to adopt an approach that would make methylene chloride paint and coating removers unobtainable to consumers, but allow continued use of methylene chloride in industrial settings. DOD Comments on MeCl and NMP at 1, EPA-HQ-OPPT-2016-0231-0519, JA__.

In 2018, Petitioner HSIA submitted a white paper to the Small Business Administration. This, too, recommended EPA consider a training, certification, and limited access program, albeit modeled on that used in the United Kingdom to a prohibition. White Paper, EPA-HQ-OPPT-2018-0844-0008, JA__.

2. 2019 Final Rule

In the Final Rule, EPA determined that "the use of methylene chloride in consumer paint and coating removal presents an unreasonable risk of injury to health due to acute human lethality." 84 Fed. Reg. at 11,421. To ensure that this use of

methylene chloride "no longer presents such risk," the Final Rule prohibits the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal, including distribution to and by retailers.[6] EPA defined "retailer" as "a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users," including through e-commerce internet sales or distribution. 84 Fed. Reg. at 11,435.[7] This includes "any person or business entity that distributes or makes available paint and coating removal products" to "at least one consumer." *Id.* at 11,429. Finally, EPA also required that manufacturers (including importers), processors, and distributors of methylene chloride for any use provide downstream notification of these prohibitions through the supply chain and conduct recordkeeping. *Id.*

EPA determined that this approach was less burdensome and more cost-effective than the primary alternative regulatory action—a restriction on the

[6] Although Environmental Petitioners have characterized this as a "ban on . . . consumer uses," EP Br. at 1, TSCA does not authorize EPA to directly ban consumer uses. *See* 15 U.S.C. § 2605(a). EPA's action bans the manufacture, processing, and distribution of methylene chloride for consumer paint and coating removal use, as permitted by Section 2605(a)(2)(A).

[7] Specifically, the regulation provides: "Any person or distributor with at least one consumer end user is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer." 40 C.F.R. § 751.103.

distribution of methylene chloride paint strippers in containers with a volume less than 55 gallons (or 5 gallons for certain formulations), along with downstream notification.[8] 84 Fed. Reg. at 11,427. EPA further concluded that there are technically and economically feasible alternatives that are available as substitutes. These include substitute chemicals and alternative methods of paint and coating removal reasonably available to consumers without the level of toxicity associated with methylene chloride. 84 Fed. Reg. 11,427–28.

Although EPA had proposed a determination that commercial paint and coating removal use presented an unreasonable risk of injury to health, EPA did not finalize that determination or promulgate any risk management measures for commercial uses. Instead, EPA issued an advanced notice of proposed rulemaking to solicit further comment on questions related to a potential training, certification, and limited access program akin to that suggested by other commenters. EPA sought to explore such an option to address any unreasonable risks that EPA could potentially find to be presented by methylene chloride when used for commercial paint and coating removal. 84 Fed. Reg. at 11,420; *see* Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program, 84 Fed.

[8] Industry Petitioners suggest that the Final Rule will limit access to methylene chloride-based paint strippers "only to businesses large enough . . . to buy and handle the product in bulk quantities of 30- or 55-gallon drums." HSIA Br. at 1. Nothing in the final rule dictates the quantities in which methylene chloride products can be sold for commercial paint and coating removal uses.

Reg. 11,466 (Mar. 27, 2019) ("ANPRM"). "Such a program could allow access to paint and coating removal products containing methylene chloride only to commercial users who are certified as properly trained to engage in use practices that do not present unreasonable risks." *Id.* at 11,466. The ANPRM solicited comment in particular on six questions, relating to the effectiveness of such a program at addressing any unreasonable risks EPA could potentially find to be presented from the commercial uses; what metrics EPA should consider in measuring the effectiveness of such a program; and whether commercial users of methylene chloride for uses other than paint and coating removal could recommend work practices, controls, and training that EPA should consider for the paint and coating removal uses, among others. *Id.* at 11,470. EPA also sought comment on many key areas of how specifically a training, certification, and limited access program could operate. *Id.* at 11,470–73.

The ANPRM explained that although EPA's Proposed Rule asked for comment on a training and certification program similar to the Lead Renovation, Repair, and Painting Rule, EPA only received one comment in response (from the Environmental Defense Fund, one of the Environmental Petitioners in this case). 84 Fed. Reg. at 11,467–68. Following the close of the comment period on the Proposed Rule, however, EPA received a White Paper from the Halogenated Solvents Industry Association—a trade association of paint and coating removal formulators that is a petitioner in this case. The White Paper discussed a potential training, certification,

and limited access program for methylene chloride in paint and coating removal. *Id.* Rather than the training and certification program similar to the lead-based paint removal program, the White Paper proposed that a methylene chloride training and certification program resembling that enacted in the United Kingdom for methylene chloride. *Id.* Under the United Kingdom's program, only trained and certified professionals may use methylene chloride for paint and coating removal and only they may purchase the chemical from specialty trade outlets. *Id.* at 11,469. This program successfully co-exists with a ban on the consumer use of methylene chloride-containing paint and coating removers. *Id.*

3. Risk evaluation of other uses

Following enactment of the 2016 TSCA amendments, on December 19, 2016, EPA published a list of 10 chemical substances that would be the subject of its initial risk evaluations in accordance with the new Section 2605(b)(2)(A), 15 U.S.C. § 2605(b)(2)(A). *See* Designation of Ten Chemical Substances for Initial Risk Evaluations Under the Toxic Substances Control Act, 81 Fed. Reg. 91,927 (December 19, 2016). Methylene chloride was one of those chemicals. *See* Scope of the Risk Evaluation for Methylene Chloride (Dkt. 7), JA__. In accordance with 15 U.S.C. § 2605(b)(4)(D), and TSCA implementing regulations, EPA subsequently published the "scope" of its methylene chloride risk evaluation, setting out the "hazards, exposures, conditions of use, and the potentially exposed or susceptible subpopulations" EPA expected to consider in the risk evaluation. 15 U.S.C.

§ 2605(b)(4)(D); Scope of Risk Evaluation ("Scope"), JA__. The Scope document, published in June 2017, noted that methylene chloride paint and coating removal uses were assessed in the 2014 Risk Assessment and were therefore considered "out of scope for the risk evaluation." Scope at 29, JA__. When the Scope document was published, those uses were already the subject of the Proposed Rule.

However, following publication of the Final Rule and the ANPRM—and following the filing of Petitioners' briefs in this case—EPA published a draft risk evaluation pursuant to 15 U.S.C. § 2605(b)(4), that *did* include methylene chloride use in commercial paint and coating removal. Draft Risk Evaluation, JA__. That Draft Risk Evaluation proposes to find that such use poses unreasonable risk of injury to health under 15 U.S.C. § 2605(b). Under the statutory deadlines set out in Section 2605(b)(4)(G), EPA must finalize this Risk Evaluation by June 2020. If EPA determines that the use of methylene chloride in commercial paint and coating removal does *not* pose unreasonable risk, that risk determination will be a final agency action subject to judicial review. *See* 15 U.S.C. §§ 2605(i)(1), 2618(a)(1)(A). If EPA finalizes the proposed determination of unreasonable risk, EPA must, under the new TSCA deadlines, propose and promulgate a risk management rule within two years, subject to the possibility of extension, as set out in 15 U.S.C. § 2605(c)(1). Any final risk management rule and related determination of unreasonable risk would also be subject to judicial review under Section 2618(a)(1)(A).

SUMMARY OF ARGUMENT

Acting under its discretionary Section 2625(*l*)(4) authority, EPA reasonably promulgated Section 2605(a) regulations restricting the manufacture (including import), processing, and distribution in commerce of methylene chloride for consumer paint and coating removal—while deferring action on commercial uses. Section 2625(*l*)(4) provides that EPA may bypass the risk evaluation process and timelines established in the 2016 TSCA amendments and publish Section 2605(a) risk management rules addressing chemicals for which EPA had previously completed a risk assessment. Here, EPA reasonably exercised that authority to prohibit the distribution of methylene chloride paint and coating removers by distributors that serve consumer customers, effectively ensuring that consumers will not be exposed to the undisputed unreasonable risk presented by consumers' use of such products. EPA's action was consistent with TSCA and should be upheld.

Environmental Petitioners contend that EPA did not go far enough. They argue that EPA should have finalized its proposed rule regarding methylene chloride for commercial paint and coating removal when finalizing the rule on consumer paint and coating removal. *See* Environmental Petitioners' Brief ("EP Br.") at 41. EPA had no duty to do so. Instead, EPA issued an ANPRM seeking comment on an alternative regulatory option to address any unreasonable risks that EPA could potentially find to be present by methylene chloride when used for commercial paint and coating removal. 84 Fed. Reg. 11,466. Since then, EPA has also issued a Draft Risk

Evaluation under 15 U.S.C. § 2605(b)(4). *See* 84 Fed. Reg. 57,866 (Oct. 29, 2019). This puts commercial use of methylene chloride in paint and coating removal, unaddressed in the Final Rule, on another administrative path subject to statutory deadlines and opportunities for judicial review. EPA has therefore not completed its decisionmaking process with respect to commercial paint and coating removal. Environmental Petitioners' claims are unreviewable and unripe.

Environmental Petitioners' argument that TSCA required EPA to act on commercial paint and coating removal misreads the statute. Section 2625(*l*)(4) provides authority—but imposes no requirement—to regulate any and all activities covered by a pre-2016 TSCA amendments risk assessment. And EPA's proposed or informal statements about the risks associated with methylene chloride use in commercial paint and coating removal do not amount to a "determination" that that activity presents "unreasonable risk." Only an unreasonable risk determination reached through the new Section 2605(b) risk evaluation process can trigger a requirement to promulgate a Section 2605(a) rule. Accordingly, EPA was not required to finalize its proposed restrictions on methylene chloride use in commercial paint and coating removal.

Finally, even if Environmental Petitioners' claims were reviewable and ripe, they fail to show that EPA's decision to solicit additional comment on options to address any unreasonable risk presented by commercial paint and coating removal was unreasonable. Congress imposed no deadline for EPA's action in this instance. EPA's

judgment that continued consideration of regulatory options is warranted is both permissible and prudent. The Court should deny Environmental Petitioners' petition for review.

HSIA's claims also fail. First, the Final Rule is a logical outgrowth of the proposal. It clarified that the proposed prohibition on distributing methylene chloride paint and coating removers for consumer use would be executed through the retailer ban. *See* 40 C.F.R. § 751.105(b) & (c). That clarification reasonably developed from the original proposal. EPA proposed to ban distribution for consumer paint and coating removal and noted its concern that consumers have ready access to methylene chloride marketed to commercial users. The proposal and the issues discussed in the Proposed Rule's preamble gave ample notice of the ultimate rule. The Final Rule was therefore a logical outgrowth.

Second, EPA adequately considered the "reasonably ascertainable economic consequences" of the Final Rule to the extent allowed by reasonably available information and by TSCA itself. 15 U.S.C. § 2605(c)(2)(A)(iv). Of the regulatory options that adequately address the unreasonable risk associated with consumer use of methylene chloride paint and coating removers, EPA selected the less costly alternative. *Id.* § 2605(c)(2)(C). And in assessing the Final Rule's regulatory impacts, EPA considered "reasonably available information" on the impact to retailers, distributors, formulators, and commercial users of methylene chloride paint and coating removers. EPA reasonably considered these issues and promulgated a rule

that ensures that the identified unreasonable risk is "no longer present," as TSCA requires. 15 U.S.C. § 2605(a).

For these reasons and the reasons that follow, both Environmental Petitioners' and HSIA's petitions should be denied.

STANDARD OF REVIEW

TSCA provides that judicial review shall be "in accordance with chapter 7 of Title 5," the Administrative Procedure Act. 15 U.S.C. § 2618(c)(1)(A). The court "shall hold unlawful and set aside such rule" only "if the court finds that the rule is not supported by substantial evidence in the rulemaking record taken as a whole." 15 U.S.C. § 2618(c)(1)(B)(i)(I); *see Corrosion Proof Fittings*, 947 F.2d at 1213.[9] Substantial evidence is "such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951). Under this standard, a court will not set aside an agency's decision so long as it is "supported by less than a preponderance but more than a scintilla of evidence." *Spring*

[9] Environmental Petitioners' statement that the Administrative Procedure Act's arbitrary or capricious standard, *see* 5 U.S.C. § 706, applies here is technically incorrect. The distinction between the substantial evidence test and the arbitrary and capricious test is, however, "largely semantic." *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. Of Governors of Fed. Reserve Sys.*, 745 F.2d 677, 683–85 (D.C. Cir. 1984); *see also id.* ("When the arbitrary or capricious standard is performing that function of assuring factual support, there is no *substantive* difference between what it requires and what would be required by the substantial evidence test, since it is impossible to conceive of a 'nonarbitrary' factual judgment supported only by evidence that is not substantial in the APA sense . . . ." (first alteration in original)).

Spectrum L.P. v. Willoth, 176 F.3d 630, 638 (2d Cir. 1999) (internal citations and quotation marks omitted). Although "[t]he reviewing court must take into account contradictory evidence in the record, . . . 'the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.'" *Am. Textile Mfrs. Inst., Inc. v. Donovan*, 452 U.S. 490, 523 (1981) (quoting *Consolo v. FMC*, 383 U.S. 607, 620 (1966)).

ARGUMENT

I. Environmental Petitioners' Claims

Environmental Petitioners contend that in finalizing only restrictions on consumer use of methylene chloride in paint and coating removal without also simultaneously finalizing action on commercial use, EPA violated TSCA and acted arbitrarily and capriciously in violation of the Administrative Procedure Act. But Environmental Petitioners' claims about EPA's lack of action fail for the very reason they challenge it: there is no final agency action to review.

First, EPA's Final Rule made clear that although it had proposed to regulate commercial use of methylene chloride in paint and coating removal, it was not making any final determination with respect to that use and was instead actively exploring alternative regulatory options. In the months since, EPA has continued its consideration. It has accepted comments on a potential training, certification, and limited access program to address any unreasonable risks that EPA could potentially find to be presented by methylene chloride when used for commercial paint and

coating removal. In addition, EPA has issued a Draft Risk Evaluation for methylene chloride under 15 U.S.C. § 2605(b)(4). This proposes to find that commercial paint and coating removal presents an unreasonable risk of injury to human health. *See* Draft Risk Evaluation, JA__. That Draft Risk Evaluation will be finalized by June 2020. If EPA determines that commercial paint and coating removal presents no unreasonable risk, it will be subject to judicial review at that time. If EPA determines, as proposed, that commercial paint and coating removal *does* present unreasonable risk, EPA will undertake the statutorily required rulemaking process set out in 15 U.S.C. § 2605(a) and (c)(1), and the resulting rule will be subject to judicial review. Thus, EPA's action on commercial use of methylene chloride in paint and coating removal remains tentative and is non-final.

Second, because EPA has not made a final determination with regard to commercial paint and coating removal and instead is actively pursuing additional administrative proceedings regarding that activity, Environmental Petitioners' claims are not ripe for review.

Third, Environmental Petitioners are wrong that TSCA requires EPA to make a final unreasonable risk determination or promulgate a final risk management rule as to commercial paint and coating removal at this time. Section 2625(*l*)(4) provides discretionary authority, in certain limited circumstances, for EPA to promulgate a Section 2605(a) risk management rule without undertaking a Section 2605(b)(4) risk evaluation. But nothing in the statute indicates that EPA must complete a proposed

rulemaking begun under that section nor imposes deadlines or other obligations under that authority.

For these reasons, as explained further below, their petition for review should be denied.

A. There is no final agency action on the use of methylene chloride for commercial paint and coating removal.

EPA has not taken final action on use of methylene chloride for commercial paint and coating removal. And absent a final agency action, TSCA does not authorize judicial review. 15 U.S.C. § 2618(c)(1)(A) (providing that courts review EPA's actions in accordance with the APA, which includes the finality requirement in 5 U.S.C. § 704).[10] Although the Agency proposed to determine that use of methylene chloride for *both* consumer and commercial paint and coating removal poses unreasonable risk, and proposed risk management restrictions to address proposed unreasonable risks from both activities, EPA only made a final risk determination with respect to consumer use. EPA explained that the Agency would seek additional comment on a potential alternative risk management approach for commercial paint and coating removal. To that end, EPA published an ANPRM the same day as the Final Rule,

[10] Congress further made clear that the APA finality standard applies to review under TSCA by stating in Section 2605(i) that specific determinations—a determination that a chemical substance does not pose unreasonable risk or issuance of a risk management rule—shall be considered final agency actions. 15 U.S.C. § 2605(i).

actively continuing the rulemaking process. 84 Fed. Reg. 11,466. Later, EPA also issued a Section 2605(b)(4) Draft Risk Evaluation for methylene chloride. In it, EPA proposed to determine the use of methylene chloride for commercial paint and coating removal presents an unreasonable risk. If finalized, such a determination would put commercial paint and coating removal uses on the amended Section 2605's new regulatory track, subject to statutory deadlines and judicial review opportunities.

An action addressing *consumer* paint and coating removal is not final agency action on *commercial* paint and coating removal. To be "final," agency action must meet two criteria: it must "mark the consummation of the agency's decisionmaking process—it must not be of a merely tentative or interlocutory nature," *Bennett v. Spear*, 520 U.S. 154, 177–78 (1997); *Pasker v. U.S. Dep't of Transp.*, 714 F.3d 90, 96 (2d Cir. 2013), and it "must be one by which rights or obligations have been determined, or from which legal consequences will flow," *Bennett*, 520 U.S. at 178. Here, Environmental Petitioners' claims fall on the first prong. EPA has not "rendered its last word on the matter," *Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 586 (1980), or made a "definitive statement of the agency's position" on the commercial use, *Pasker*, 714 F.3d at 97 (quoting *Air Cal. v. U.S. Dep't of Transp.*, 654 F.2d 616 (9th Cir. 1981)). Accordingly, there is no reviewable agency action. Environmental Petitioners' claims should be denied.

1. EPA's decisionmaking process on commercial paint and coating removal is incomplete.

Though the Final Rule embodies EPA's final determination and regulation of *consumer* paint and coating removal, EPA's determination on *commercial* paint and coating removal remains "tentative." The Final Rule specifically noted the EPA was not finalizing a risk determination for commercial paint and coating removal and was instead issuing an ANPRM on additional risk management options for that use. EPA indicated the same in its Response to Comments, stating that the Proposed Rule's statements about commercial paint and coating removal were "preliminary, not final." Response to Comments at 4, JA__; *see also id.* at 51, JA__ ("EPA will address commercial paint and coating removal in the future."). Instead, EPA explained it would solicit additional comment through an ANPRM on an alternative regulatory approach: rather than a commercial use and distribution ban, the ANPRM seeks comment on a training, certification, and limited access program. 84 Fed. Reg. at 11,420. EPA thus clearly indicated that it had not "completed its decisionmaking process" with respect to regulating commercial paint and coating removal. *Franklin v. Massachusetts*, 505 U.S. 788, 797 (1992).

EPA has actively continued its decisionmaking process on commercial paint and coating removal since the Final Rule was published. In addition to the ANPRM, in October of 2019, EPA published a draft risk evaluation for methylene chloride under the new Section 2605(b)(4) process. That Draft Risk Evaluation includes

commercial paint and coating removal that was addressed in the Proposed Rule and proposes to determine that such use presents unreasonable risk of injury to health. The proposed unreasonable risk determination in the Draft Risk Evaluation continues the administrative process on commercial paint and coating removal. Because of the statutory deadlines for Section 2605(b) risk evaluations, EPA must make a final determination about whether the commercial uses present unreasonable risks by June 2020. *See* 15 U.S.C. § 2605(b)(4)(G). If EPA determines the use of methylene chloride in commercial paint and coating removal does not present unreasonable risks, *that* determination would be final action subject to judicial review. And if EPA determines this commercial use *does* pose unreasonable risk, the Agency must propose and promulgate a risk management rule within two years, subject to the possibility of extension, as set out in 15 U.S.C. § 2605(c)(1). Any final risk management rule subsequently issued would also be final action subject to judicial review. *Id.* § 2618(a)(1)(A).

This case is similar to *Environmental Defense Fund, Inc. v. Johnson*, 629 F.2d 239 (2d Cir. 1980), in which the court found that the Army Corps of Engineers' report seeking funds to further study a highway project was not reviewable final agency action. The court noted that the Corps' report simply requested additional funds to study the project further and did not recommend any "definitive" action. The Court concluded that the report was not final agency action; indeed, the study "may reaffirm [the highway project], reform it, or even recommend that it not be constructed." *Id.* at 241.

Given that the fate of the highway project remained unresolved and uncertain, the court concluded that judicial intervention would be "a waste of judicial resources" and "an untoward interference in the administrative process." *Id.*

The same is true here. The final action challenged here makes no determination whether the use of methylene chloride for commercial paint and coating removal poses unreasonable risk. The action also makes no determination whether risk management restrictions for commercial paint and coating removal are necessary. Rather, EPA is taking steps to study the problem further. EPA sought further comment on a different risk management approach so that it can better assess what restrictions could be used to ensure commercial paint and coating removal "no longer present[s]" any unreasonable risk the Agency may find to exist. 15 U.S.C. § 2605(a). In addition, by including commercial paint and coating removal in its Section 2605(b)(4) Draft Risk Evaluation, EPA has taken additional concrete steps toward regulating the commercial uses, if the Agency determines that such use presents unreasonable risk. And when EPA makes a final determination with respect to such unreasonable risk, *that* determination will be ripe for judicial review or will trigger a statutory duty to issue risk management regulations.

Judicial intervention at this time would disrupt EPA's ongoing administrative process, exactly what the finality requirement is designed to avoid. This court has stated that the finality requirement must be interpreted pragmatically, "with an eye toward protecting agencies from the disruption of piecemeal appeals and toward

insuring that judicial review involves concrete disputes over meaningful interests, rather than abstract disputes over hypothetical governmental actions." *Nat'l Wildlife Fed'n v. Goldschmidt*, 677 F.2d 259, 263 (2d Cir. 1982). That sort of "abstract dispute" is what would happen here. EPA's action on commercial paint and coating removal remains tentative; it has continued exploring regulatory options to address the potential risk presented by this use, and has put commercial paint and coating removal on a concrete path toward either a final no unreasonable risk determination or a final unreasonable risk determination coupled with a forthcoming risk management rule to eliminate the unreasonable risk (actions that Congress identified as final agency action, 15 U.S.C. § 2605(i)). That final determination and potential subsequent regulation may moot or significantly change the issues Environmental Petitioners have raised here. Judicial review now is unnecessary and counterproductive.

Indeed, the fact that Environmental Petitioners will have time and opportunity to challenge the final risk evaluation or, if applicable, a final risk management rule later in the process is a reason courts have declined to find finality in the past. In *Goldschmidt*, 677 F.2d at 263, for example, the court did not find an agency action final and therefore reviewable, noting that it was "unable to detect any legal issue our decision will foreclose [the issue raised] from challenge if and when a decision to [act] is made." In that case, as here, "[r]eview now might well adjudicate matters which are ultimately immaterial and would by no means put the matter to rest." *Id.*; *see also City of Fall River, Mass. v. FERC*, 507 F.3d 1, 7 (1st Cir. 2007) (noting that "[a]ppellants retain

every opportunity to challenge FERC's decision in the event the USCG and DOI approve the project").

Moreover, although, in some circumstances, agency inaction can be "the functional equivalent" of final agency action and therefore reviewable as such, *see Am. Anti-Vivisection Soc'y v. U.S. Dep't of Agric.*, 351 F. Supp. 3d 16, 26 (D.D.C. 2018) (internal quotation omitted), *rev'd on other grounds*, 946 F.3d 615 (D.C. Cir. 2020), that is not the case here. For instance, this is not a case like *Fox Television Stations, Inc. v. FCC*, 28 F.3d 1027 (D.C. Cir. 2002), in which the agency made an affirmative decision *not* to engage in rulemaking to repeal or modify an existing rule. Here, by contrast, the Final Rule's lack of action on commercial paint and coating removal did not evince any determination that there should or will be no action on that use in the future. Rather, through the ANPRM and the Draft Risk Evaluation, EPA has continued to engage in the administrative process, "repeatedly reiterate[ing] its intention" to act on methylene chloride use in commercial paint and coating removal. *Am. Anti-Vivisection Soc'y v. U.S. Dep't of Agric.*, No. 19-5015, slip op. at 8 (D.C. Cir. Jan. 10, 2020) (to be published at 946 F.3d 615). Even if Environmental Petitioners believe action on commercial paint and coating removal has been too-long delayed, here, as in *American Anti-Vivisection*

Society, EPA's "decisionmaking process . . . remains unconsummated." *Id.* There is no reviewable final agency action.[11]

2. Judicial review now is contrary to TSCA's statutory scheme.

To allow review of Environmental Petitioners' claims now would also subvert TSCA's statutory scheme. Environmental Petitioners contend that the record shows that *any* use of methylene chloride for paint and coating removal is dangerous and therefore declining to act on commercial use by finalizing the Proposed Rule's approach was arbitrary and capricious. EP Br. at. 46. But TSCA does not create a requirement to make determinations on and regulate unreasonable risks except as set out in the Section 2605(b) risk evaluation process. Here, EPA was not acting under Section 2605(b) and, as discussed further below, did not make an "unreasonable risk" determination that would require EPA to take action under Section 2605(a). *See infra* Part I.C.2. Rather, EPA proposed to exercise the discretionary authority in Section 2625(*l*)(4) for commercial paint and coating removal—and it simply has declined to exercise that authority as of yet.

Granting review of Environmental Petitioners' claims would therefore erase the distinction between Section 2605(b) and Section 2625(*l*)(4). It would impose an

[11] In *American Anti-Vivisection Society*, 946 F.3d 615, the D.C. Circuit recently remanded for the district court to consider plaintiffs' unreasonable delay claims raised under 5 U.S.C. § 706(1). Environmental Petitioners have not brought such a claim here.

obligation to act where the statute creates none. Section 2625(*l*)(4) merely *authorizes* EPA to proceed to risk management for certain chemical substances for which EPA published a completed risk assessment prior to the effective date of 2016 TSCA amendments. *See* 15 U.S.C. § 2625(*l*)(4) ("[T]he Administrator *may* publish proposed and final rules under section 2605(a) of this title that are consistent with the scope of the completed risk assessment for the chemical substance . . . ."). It does not *require* EPA to issue risk management rules. Nor does it require that any risk management rules promulgated under its authority cover the full scope of the completed risk assessment. Taking action on one activity covered by the risk assessment should not open the door to judicial review of preliminary, non-final action on another.

In the end, Environmental Petitioners do not contend EPA's final *action* was unreasonable. They implicitly contend that EPA's continued consideration without *action* at this time is unreasonable. But that is not "final agency action" where there is no duty to act. In any event, EPA has continued its decisionmaking process by issuing a Draft Risk Evaluation that encompasses use of methylene chloride in commercial paint and coating removal.

In sum, there has been no final agency action on commercial paint and coating removal products containing methylene chloride. Environmental Petitioners' claims are unreviewable and their petition for review must be dismissed.

B. Given EPA's ongoing administrative process and imminent action on commercial paint and coating removal, Environmental Petitioners' claims are not ripe for review.

Environmental Petitioners' claims also seek review of action—EPA's alleged inaction on commercial paint and coating removal—that is not yet ripe for judicial review. Ripeness is a justiciability doctrine "drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *Reno v. Catholic Social Servs., Inc.*, 509 U.S. 43, 57 n.18 (1993). Ripeness doctrine "prevent[s] courts, through avoidance of premature adjudication, from entangling themselves in abstract disagreements over administrative policies" and also "protect[s] the agencies from judicial interference until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Abbott Labs. v. Gardner*, 387 U.S. 136, 148–49 (1967). Here, EPA decisions related to whether and, if warranted, how to regulate commercial paint and coating removal have not yet been made and the Agency is still actively engaged in its decisionmaking process. Adjudicating the reasonableness of having *not* yet regulated methylene chloride use in commercial paint and coating removal is therefore premature and Environmental Petitioners' claims are unripe.

To determine whether a claim is ripe, courts consider the "fitness of the issues for judicial decision," which involves an inquiry into "whether the court or agency would benefit from postponing review until the policy in question had sufficiently crystallized." *Fla. Power & Light Co. v. EPA*, 145 F.3d 1414, 1421 (D.C. Cir. 1998).

Second, if a challenged decision is not "fit" for review, courts must consider whether postponing review will cause the petitioner "hardship." *Id.* Under this test, "if the interests of the court and agency in postponing review outweigh the interests of those seeking relief, settled principles of ripeness squarely call for adjudication to be postponed." *Nat'l Ass'n of Regulatory Util. Comm'rs v. Dep't of Energy*, 851 F.2d 1424, 1428 (D.C. Cir. 1988).

Additionally, in the case of prudential ripeness, this court has noted that "when a court declares that a case is not prudentially ripe, it means that the case will be *better* decided later . . . [not] that the case is not a real or concrete dispute affecting cognizable current concerns of the parties." *N.Y. Civil Liberties Union v. Grandeau*, 528 F.3d 122, 131 (2d Cir. 2008). "Prudential ripeness is, then, a tool that courts may use to enhance the accuracy of their decisions and to avoid becoming embroiled in adjudications that may later turn out to be unnecessary or may require premature examination of" the issues presented. *Connecticut v. Duncan*, 612 F.3d 107, 113–14 (2d Cir. 2010) (quoting *N.Y. Civil Liberties Union*, 528 F.3d at 131).

Environmental Petitioners' claims fail to meet either the fitness or hardship conditions for ripeness. First, they are not yet "fit" for judicial review. The "fitness" requirement "is primarily meant to protect the agency's interest in crystallizing its policy before that policy is subjected to judicial review and the court's interests in avoiding unnecessary adjudication and in deciding issues in a concrete setting." *Am. Petroleum Inst. v. EPA*, 683 F.3d 382, 387 (D.C. Cir. 2012). Here, EPA has plainly not

"crystalliz[ed]" its policy with respect to use of methylene chloride in commercial paint and coating removal. The Final Rule made no final determination as to whether commercial paint and coating removal presents an unreasonable risk. EPA has since incorporated commercial paint and coating removal into its draft risk evaluation for methylene chloride and has proposed to determine that commercial paint and coating removal presents an unreasonable risk.

Given this state of affairs, review now would be premature and would unnecessarily entangle the court in an ongoing administrative process. The ripeness doctrine "ensures that Article III courts make decisions only when they have to, and then, only once." *Am. Petroleum Inst.* 683 F.3d at 387; *see also Murphy v. New Milford Zoning Comm'n*, 402 F.3d 342, 347 (2d Cir. 2005) ("At [ripeness doctrine's] heart is whether we would benefit from deferring initial review until the claims we are called on to consider have arisen in a more concrete and final form."). In short order—indeed, by June 2020—EPA will make a final determination as to whether and how commercial paint and coating removal presents an unreasonable risk of injury to health or the environment. If the Agency determines it does not, then that decision is final agency action subject to judicial review. 15 U.S.C. § 2605(i)(1).

Declining to review EPA's purported inaction on commercial paint and coating removal now would thus "avoid[] unnecessary adjudication" because EPA must take final action on the Draft Risk Evaluation by June 2020. *Fla. Power & Light Co.*, 145 F.3d at 1421. At that point, the questions Environmental Petitioners seek to

adjudicate now will be presented in a more "concrete setting," *id.*, where EPA will have expressly made a determination whether or not the use of methylene chloride in commercial paint and coating removal poses an unreasonable risk and therefore requires risk management. If EPA makes a determination of no unreasonable risk, it will be reviewable final action. 15 U.S.C. § 2605(i)(1). If EPA makes an unreasonable risk determination, EPA would be required to begin a risk management rulemaking by operation of Section 2605(c)(1), and its final risk management rule will be final action subject to review. 15 U.S.C. § 2605(i)(2). The Agency's ultimate decision, therefore, is in flux and will be made more concrete imminently. Given "the interest in postponing review is powerful when the agency position is tentative," *Ciba-Geigy Corp. v. EPA*, 801 F.2d 430, 436 (D.C. Cir. 1986), these facts weigh strongly against finding Environmental Petitioners' claims ripe for review now.

Review here would be even more premature than in *American Petroleum Institute v. EPA*, 683 F.3d at 388. There, EPA had issued a 2008 rule regulating certain petroleum refinery materials but declining to deregulate a category of materials called spent refinery catalysts, electing instead to "address the catalysts in a separate proposed rulemaking." *Am. Petroleum Institute*, 683 F.3d at 386. Shortly after the case was fully briefed, EPA published a notice of proposed rulemaking to revise the challenged rule and deregulate the catalysts. If the proposed rule were finalized, the case would "go[] away without the need for judicial review." *Id.* at 388. Accordingly, even though the D.C. Circuit found that the 2008 regulation was a reviewable "final

rule," it concluded that the case was not ripe because EPA's position on the policy being challenged was "plainly a tentative one." *Id.* at 387–88. *See also Belmont Abbey College v. Sebelius*, 878 F. Supp. 2d 25, 40 (D.D.C. 2012) (finding claim unripe where "the ideas and questions raised in the ANPRM appear to be the product of significant research and deliberation" and the agency had "formally committed to amending the rule before the safe harbor expires, thereby creating external accountability for the agency's self-imposed deadline"). Given EPA's ongoing administrative process, subject to statutory deadlines, the state of affairs with respect to EPA's action or inaction on methylene chloride in commercial paint and coating removal is even more "plainly . . . tentative" here.

As in *American Petroleum Institute*, EPA is not merely paying lip service to the possibility of further action; rather, the "possibility that further consideration will actually occur . . . is not theoretical, but real." *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 735 (1998). EPA's continued consideration of administrative options—first through the ANPRM exploring risk management options and then through the Draft Risk Evaluation advancing commercial paint and coating removal through the new Section 2605(b)(4) process—is "clearly not some non-substantive, thinly veiled attempt to evade review." *American Petroleum Institute v. EPA*, 683 F.3d at 388. Rather, given the statutory deadline to finalize a risk evaluation by June 2020, and additional rulemaking deadlines that follow, the prospect of final agency action on the

commercial use at issue here is *more* certain than even the proposed rule at issue in *American Petroleum Institute*. The Court should accordingly decline review at this time.

These prudential considerations are sufficient grounds for finding Environmental Petitioners' claims are not "fit" for review. In addition, some of those claims would benefit from further development of the administrative record and EPA's explanation of its decision—when such a decision is finally made. For example, Environmental Petitioners contend that EPA did not sufficiently explain its purported "exclusion" of commercial paint and coating removal from the Final Rule, EP Br. at 42–43, and failed to consider the effects of that "exclusion" on commercial workers and bystanders, EP Br. at 48–50. But given EPA has not taken the action that Environmental Petitioners claim was insufficiently explained or supported, the Court would benefit from considering the questions presented by Environmental Petitioners' claims once EPA has developed a record for whatever action the Agency decides to take.

In addition, Environmental Petitioners will suffer little hardship from postponing judicial review until EPA makes decisions affecting whether to take action and, if warranted, what action to take. In evaluating the hardship prong of the prudential ripeness doctrine, courts "do not consider 'direct hardship,' but rather whether *postponing* judicial review would impose an undue burden on [the parties] or would benefit the court." *Full Value Advisors LLC v. SEC*, 633 F.3d 1101, 1106 (D.C. Cir. 2011) (quoting *Harris v. FAA*, 353 F.3d 1006, 1012 (D.C. Cir. 2004)). Postponing

review here will not impose an undue burden. In fact, delaying review will allow the very administrative process that Environmental Petitioners seek to compel here—potential rulemaking on commercial paint and coating removal—to take place without judicial interferences. Environmental Petitioners request that the Court compel EPA "to issue a revised final rule under TSCA Section 6(a) that is consistent with the findings of the Risk Assessment." EP Br. at 65. Environmental Petitioners suggest that EPA has already made an unreasonable risk determination. For the reasons discussed in Part I.A., *supra*, it has not. But even if EPA had, Petitioners' request for relief would essentially be for EPA to conduct the sort of rulemaking that may ultimately result from the Section 2605(b) risk evaluation process already under way. If EPA finalizes the proposed unreasonable risk determination for commercial use of methylene chloride in paint and coating removal from the Draft Risk Evaluation—and it must make a final risk determination by June 2020—then EPA must propose and promulgate risk management rules according to the Section 2605(c) statutory deadlines. In short, Environmental Petitioners will not suffer undue hardship from deferring review for the many compelling reasons described above. Environmental Petitioners' claims are therefore unripe. Their petitions for review should be denied.

C. Neither Section 2625(*l*)(4) nor Section 2605(a) imposes an obligation to finalize a rule regulating the use of methylene chloride for commercial paint and coating removal.

Environmental Petitioners attempt to avoid the finality and ripeness problems discussed above by arguing that TSCA *required* EPA to regulate commercial paint and

coating removal. They wrongly contend EPA determined that methylene chloride poses an unreasonable risk of injury to health. EP Br. at 30–31. EPA did not. Petitioners' argument misreads the statute and the record.

Neither Section 2625(*l*)(4) nor Section 2605(a) required EPA to promulgate risk management regulations for commercial methylene chloride paint stripping activities at this time. Section 2625(*l*)(4) is a discretionary grant of authority. It authorizes EPA to promulgate a risk management rule if EPA determines unreasonable risk based on a pre-2016 risk assessment; it does not obligate EPA to do so. While Section 2605(a) does impose mandatory requirements, it was not triggered in the circumstances presented here. In short, EPA did not violate TSCA by exercising the discretion Congress afforded it to explore a different regulatory approach before taking final action to regulate commercial uses.

1. Section 2625(*l*)(4) authorizes EPA to issue a Section 2605(a) risk management rule, but it does not require EPA to do so.

In the Proposed Rule, EPA proposed to exercise its discretionary authority under 15 U.S.C. § 2625(*l*)(4) to regulate methylene chloride use in commercial paint and coating removal, "for which the Administrator has published a completed risk assessment prior to June 22, 2016." Section 2625(*l*)(4) does not *require* EPA to promulgate risk management rules for chemicals that meet this requirement. Rather, it *allows* EPA, in its discretion, to promulgate such rules without going through the amended TSCA's Section 2605(b) risk evaluation process. In other words, for

substances already assessed under pre-amendment TSCA, Congress allowed EPA to avoid the structure and requirements of risk evaluation. EPA could instead apply its regulatory judgment directly in a risk management rule for a narrow set of chemicals for which EPA had already completed the scientific heavy lifting. Accordingly, when EPA did not finalize the risk management restrictions it had proposed to address commercial paint and coating removal, it did not run afoul of any statutory requirement.

Section 2625(*l*)(4)'s permissive rather than restrictive thrust is made clear in the statutory text. That provision states that EPA "*may* publish proposed and final rules" consistent with applicable requirements of Section 2605. Congress did not use "shall" or "must" or any other language suggesting a requirement to act. Accordingly, Environmental Petitioners' argument that, once proposed, EPA had a duty to finalize risk management restrictions for commercial paint and coating removal misconstrues Congress's intent.

Reading Sections 2625(*l*)(4) and Section 2605(b) side-by-side makes clear Congress intended to *allow* but not *mandate* regulation under Section 2625(*l*)(4). The new Section 2605(b) risk evaluation process *does* require EPA to issue proposed and final risk management rules once a risk evaluation is complete and concludes that a chemical substance presents an unreasonable risk under the conditions of use. *See* 15 U.S.C. § 2605(c)(1). And once EPA issues a final risk evaluation finding that a chemical substance poses unreasonable risk under the conditions of use, it is obligated

to propose and promulgate risk management restrictions listed under Section 2605(a) to ensure the chemical substance no longer presents unreasonable risk. Section 2605(b) demonstrates that Congress knows how to create a requirement to act in a certain way, and thus that it did not do so in Section 2625(*l*)(4).

Environmental Petitioners contend that EPA was obligated to finalize a rule with respect to commercial paint and coating removal because it was within the "scope" of the 2014 Risk Assessment. But that is not what Section 2625(*l*)(4) says. Section 2625(*l*)(4) states EPA "*may*" publish rules "consistent with the scope" of final risk assessments predating the 2016 TSCA amendments. 15 U.S.C. § 2625(*l*)(4). It does not state that EPA "*must*" or "may *only*" publish rules that are coextensive with the risk assessment's scope. Thus, the reference to the "scope" of the risk assessment is a limitation on when EPA may promulgate risk management regulations using pre-existing risk assessments, skipping the Section 2605(b) risk evaluation process. EPA cannot regulate any activities or conditions of use *not* in the scope of the risk assessment. But there is no requirement that EPA publish a risk management rule for any activity or condition of use within the scope of a risk assessment. A risk assessment's "scope" provides a ceiling but does not set a floor.

The permissive rather than restrictive interpretation of the "scope" language in Section 2625(*l*)(4) comports with Congress's intent as explained in legislative history. Explaining their reasoning for creating the Section 2625(*l*)(4) alternative path to risk management regulations, the Senate conference negotiators noted that EPA had

completed some risk assessments for some conditions of use. 162 Cong. Rec. at S3518-19. The negotiators then explained that, "[d]uring the bi-cameral negotiations," Congress considered EPA's view that "rather than reexamine and perhaps broaden the scope of these [existing risk] assessments, it is better to proceed with proposed and final rules on the covered chemicals." 162 Cong. Rec. at S3519 col. 1. The Section 2625(*l*)(4) language was thus added, at EPA's request, "to *allow* EPA to proceed with the regulation of these substances . . . ." *Id.* (emphasis added). The legislative history makes no mention of a *requirement* for or even an *expectation* that EPA would regulate through this provision. Even if the intent was to provide an alternative, and more streamlined route to regulation, Congress plainly did not expect that EPA *must* regulate the already assessed chemicals in this way. Section 2625(*l*)(4) neither required EPA to regulate based on the existing risk assessments nor required EPA to act on *all* assessed activities in one rule under that authority.

EPA has invariably interpreted its Section 2625(*l*)(4) authority consistent with that understanding of Congressional intent. For instance, when EPA issued regulations for trichloroethylene ("TCE") under Section 26(*l*)(4), it proposed separate rules for different circumstances—it did not interpret its authority as requiring one single rule covering all of the uses in that chemical's risk assessment. *See* Trichloroethylene (TCE); Regulation of Use in Vapor Degreasing under TSCA Section 6(a), 82 Fed. Reg. 7432 (Jan. 19, 2017); Trichloroethylene (TCE); Regulation of Certain Uses under TSCA § 6(a), 82 Fed. Reg. 10,732 (Feb. 15, 2017). Here, EPA

reiterated that its Section 2625(*l*)(4) authority is discretionary. *See* 84 Fed. Reg. at 11,425; *see also* Response to Comments at 13, JA__ ("EPA agrees that section [2625(*l*)(4)] does not impose deadlines for issuance of rules promulgated under that authority."). Thus, to the extent the statutory text is not clear, EPA's interpretation is entitled to deference. *See Skidmore v. Swift & Co.*, 323 U.S. 134 (1944).

Environmental Petitioners contend that EPA's interpretation of "scope" leaves a regulatory gap in which conditions of use may be regulated neither through Section 2625(*l*)(4) nor through the Section 2605(b) risk evaluation process. But no such gap exists here. Nothing in the statute *prevents* EPA from evaluating circumstances addressed in a risk assessment under the new risk evaluation process. And nothing prevents EPA from addressing circumstances that *could* have been addressed through Section 2625(*l*)(4) in a Section 2605(b) risk evaluation. In fact, that is what EPA is doing now: EPA has incorporated commercial paint and coating removal into its Section 2605(b) risk evaluation for methylene chloride and has proposed to determine that the use presents an unreasonable risk. Draft Risk Evaluation, JA__. Because EPA was not required to take any action on commercial paint and coating removal, its failure to do so here is not reviewable final agency action.[12]

[12] For the same reason, North American Building Trades Union's ("NABTU") argument, *see* NABTU Br. at 20–26, that deferring finalizing a rule with respect to commercial use of methylene chloride in paint and coating removal violates TSCA fails. First, action under Section 2625(*l*)(4) is not subject to any statutory deadlines, so deferring action as EPA did here does not violate any statutory command. Second,

Environmental Petitioners' argument to the contrary rests on the faulty premise that Section 2625(*l*)(4) imposes on EPA a binary choice: either regulate a chemical substance in all its conditions of use covered by the pre-2016 TSCA amendments risk assessment through Section 2625(*l*)(4), or proceed with a new risk evaluation under Section 2605(b). *See* EP Br. at 38. But that interpretation converts the permissive language of Section 2625(*l*)(4) into a requirement out of sync with the statutory text and Congressional intent. Nothing in Section 2605(*l*)(4) requires EPA to address every condition of use in a single rulemaking requires. And nothing prevents EPA from evaluating conditions of use that are within the scope of a risk assessment under a new Section 2605(b)(4) risk evaluation. Indeed, EPA's Draft Risk Evaluation for methylene chloride shows that, after declining to finalize the Proposed Rule under its Section 2625(*l*)(4) authority, EPA incorporated commercial paint and coating removal into the Section 2605(b)(4) process.

In sum, here, EPA exercised the discretion Congress granted to promulgate a rule "consistent with the scope" of the pre-existing risk evaluation. The rule addresses an activity—consumer paint and coating removal—that was covered by the Risk

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NABTU's suggestion that EPA will violate deadlines relevant to Section 2605(b) risk evaluations is, on the one hand, irrelevant to the action at issue here and, on the other, belied by the Draft Risk Evaluation for methylene chloride. The Draft Risk evaluation, which proposes to find that the commercial use of methylene chloride in paint and coating removal presents an unreasonable risk, will be finalized by June 2020, in accordance with TSCA's statutory deadlines.

Assessment. EPA later determined, on the basis of that Risk Assessment, this consumer use presented an unreasonable risk of injury to human health. By that same token, EPA permissibly deferred action on commercial paint and coating removal pending further administrative proceedings. The Court should therefore deny Environmental Petitioners' petition for review.

2. Section 2605(a) does not require the Agency to act where EPA has not made an unreasonable risk determination.

Section 2605(a) states that EPA "shall . . . apply" risk management requirements "[*i*]*f* the Administrator determines in accordance with subsection (b)(4)(A)" that a chemical substance presents an "unreasonable risk of injury to health or the environment." 15 U.S.C. § 2605(a). EPA has not determined in accordance with Section 2605(b)(4) that the use of methylene chloride in commercial paint and coating removal presents an unreasonable risk. *See* 84 Fed. Reg. at 11,421 (stating EPA was "not finalizing the proposed unreasonable risk determination"). Accordingly, it has not triggered any requirement to adopt risk management restrictions under Section 2605(a).

Environmental Petitioners' argument, *see* EP Br. at 31, that the 2014 Risk Assessment triggered a duty to apply Section 2605(a) risk management restrictions is incompatible with the statutory text. By its terms, Section 2605(a) only requires EPA to promulgate risk management restrictions if EPA "determines *in accordance with subsection (b)(4)(A)*"—in other words, through a risk evaluation—that a chemical

substance under specified conditions of use presents "unreasonable risk[s]." 15 U.S.C. § 2605(a).[13] As noted, EPA has issued a Draft Risk Evaluation under Section 2605(b)(4) for methylene chloride; but that risk evaluation is not yet final. Therefore, the requirement to promulgate risk management restrictions for methylene chloride consumer uses has not been triggered.

Despite the unambiguous statutory language of Section 2605(a), Environmental Petitioners inappropriately conflate a risk *assessment* with a risk *evaluation*. A "risk assessment" describes the probability that adverse health or ecosystem effects of specific types will occur under specific conditions of exposure to, in this case, a chemical substance. *See* 82 Fed. Reg. 33,726, 33,746 & n.9 (July 20, 2017) (citing National Academy of Sciences, Science and Decisions: Advancing Risk Assessment). As such, it provides scientific analysis but does not include any policy-based risk determinations with any regulatory impact. Pre-amendment TSCA did not require EPA to conduct these assessments and a risk assessment's findings did not—and do not now—create any obligation or deadline for EPA to act under Section 2605. And although EPA could rely on a risk assessment as a basis for risk-management action prior to the 2016 TSCA amendments, the assessment itself did not embody a

[13] As discussed above, EPA *may* proceed to risk management without conducting a Section 2605(b) risk evaluation as provided under Section 2625(*l*)(4) and in certain other circumstances not relevant here, such as in response to a citizen petition for rulemaking under 15 U.S.C. § 2620, and action on certain persistent, bioaccumulative, and toxic chemicals under 15 U.S.C. § 2605(h).

regulatory determination that a chemical substance presents "unreasonable risks" within the meaning of 15 U.S.C. § 2605(a).

"Risk evaluations," by contrast, *do* have regulatory import. A "risk evaluation" is a specialized term under the 2016 TSCA amendments, referring to the process contemplated by Section 2605(b)(4). As set forth in EPA's rule establishing procedures for conducting risk evaluations under amended TSCA, the risk evaluation process uses scientifically accepted tenets of risk assessment and ultimately culminates in a policy-based determination of whether a chemical substance presents an unreasonable risk of injury to health or the environment (or a "risk determination") under the conditions of use. *See* Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act ("Risk Evaluation Rule"), 82 Fed. Reg. 33,726 (July 20, 2017). In other words, risk evaluations are both science-based risk assessments *and* communicate a policy-based determination, informed by science, of whether a chemical substance under a particular condition of use poses "unreasonable risk" within the meaning of Section 2605(a). An unreasonable risk determination in a risk evaluation triggers the requirement for EPA to promulgate risk management regulations under Section 2605(a) pursuant to the deadlines set out in Section 2605(c)(1). This is the process through which EPA has now proposed to determine

the commercial use at issue here presents an unreasonable risk, and on which EPA must take final action by June 2020.[14]

TSCA's plain text similarly upends Environmental Petitioners' argument that EPA has made a "de facto" unreasonable risk determination, triggering a Section 2605(a) obligation to regulate commercial paint and coating removal. *See* EP Br. at 35–37. Environmental Petitioners point to two cases in which the Southern District of New York and then the Second Circuit recognized that "the 'functional equivalent' of formal findings" could trigger a requirement for EPA to propose a chemical testing rule under 15 U.S.C. § 2603. *See Physicians Comm. for Responsible Med. v. Johnson*, 436 F.3d 326, 328 (2d Cir. 2006); *Nat. Res. Def. Council, Inc. v. EPA*, 595 F. Supp. 1255, 1261 (S.D.N.Y. 1984). Section 2603 provides that if EPA made certain "find[ings]" with respect to a chemical substance or mixture, it must "require that testing be conducted on such substance or mixture." 15 U.S.C. § 2603(a). In *Physicians Committee* and *NRDC*, the courts found that when EPA has made "*de facto* findings on certain chemicals, it would subvert the statutory scheme to allow the agency to excuse itself

[14] Amicus NABTU similarly misunderstands the distinction between risk evaluation and risk assessment. It argues, for instance, that EPA erred in seeking additional comment on risk management options for commercial paint and coating removal because the Agency is barred from considering factors not related to health or the environment "when performing section [2605(b)] risk evaluations." NABTU Br. at 14–15. But neither the Proposed Rule nor the risk management option described in the ANPRM are a Section 2605(b) risk evaluation. NABTU's argument is inapposite.

from the statute's rulemaking mandate through its failure to make formal findings." *Physicians Comm.*, 436 F.3d at 328. Notably, Section 4 did not specify a process by which the required "findings" would or must be made.

By contrast, Section 2605(a) *does* state how the unreasonable risk "determination" that triggers rulemaking requirements is to be made. It states:

> 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 . . . presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule . . . apply one or more of the following requirements to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents such risk[.]

15 U.S.C. § 2605(a). The statute therefore precludes an informal or purported "de facto" determination that a chemical substance presents unreasonable risks from triggering the Section 2605(a) rulemaking requirement; only a determination made "*in accordance with* subsection (b)(4)(A)" can do that.

Environmental Petitioners and Amicus NABTU contend that various public statements and record documents evince EPA's true "determination" of unreasonable risk. These arguments fail because none of these constitute a determination under Section 2605(b)(4)(A). Indeed, none of the statements or documents petitioners rely on are "determinations." The discussion of unreasonable risk in the Proposed Rule was, as the name suggests, a *proposed* finding of unreasonable risk. *See* Response to Comments at 4, JA__ (the Proposed Rule's statements about commercial uses were "preliminary, not final"); *see Nat. Res. Def. Council v. EPA*, 706 F.3d 428, 433 (D.C. Cir.

2013) (finding "Interim Implementation Policy" was not final agency action because it represented EPA's "preliminary view" (internal quotation omitted)). The Proposed Rule states that "EPA *proposes* a determination that the uses of methylene chloride . . . in paint and coating removal present an unreasonable risk of injury to health." 82 Fed. Reg. at 7465. Statements about risk in the proposal are not a *determination* with respect to risk, but rather an explanation for why EPA is proposing such a determination.

Statements in the Proposed Rule that make its proposed, tentative status clear on its face cannot, then, create a requirement to act under Section 2605(a). This is true particularly where EPA has "expressed intent to issue a final, binding notice-and-comment rule on the issue." *Nat. Res. Def. Council*, 706 F.3d at 433. EPA has expressed similar intent here: first in the ANPRM, where it has sought comment on an alternative risk management option for commercial paint and coating removal; and second in incorporating use of methylene chloride in commercial paint and coating removal into the methylene chloride Draft Risk Evaluation.

Moreover, adopting Environmental Petitioners' and Amicus' position that EPA's preliminary statements about unreasonable risk were actually binding, final determinations would upend the requirement in Section 2625(*l*)(4) that EPA "publish proposed and final rules" to impose requirements under Section 2605(a). Finding that a *proposed* determination binds the agency and obligates it to regulate would prevent EPA from reassessing or revising a proposal in response to public comment, new information, or scientific peer review. Such an outcome is plainly contrary to

administrative law principles of notice and comment under which an agency must "maintain[ ] a flexible and open-minded attitude." *McLouth Steel Prods. Corp. v. Thomas*, 838 F.2d 1317, 1325 (D.C. Cir. 1988); *see also Horsehead Res. Dev. Co., Inc. v. Browner*, 16 F.3d 1246, 1267–68 (D.C. Cir. 1994) (noting that an important purpose of comment is "to promote informed decisionmaking").

Indeed, this court in *Environmental Defense Fund v. Thomas*, 870 F.2d 892, 899 (2d Cir. 1989), rejected the same type of argument Environmental Petitioners advance here. In *Thomas*, environmental groups contended that an EPA report on adverse effects caused by a particular air pollutant was, in effect, "a formal declaration" that revising air quality standards for that pollutant was "appropriate" under Section 109(d) of the Clean Air Act. *Thomas*, 870 F.3d at 899. The *Thomas* petitioners contended that EPA had "impliedly found revision to be 'appropriate,'" and thus had a non-discretionary duty to revise air quality standards consistently with the implied "determination." *Thomas*, 870 F.2d at 899. The Court rejected this argument—as it should reject Environmental Petitioners' argument here.

As in *Thomas*, neither informal statements by EPA officials nor proposed action by the Agency amounts to a "determination" that commercial use of methylene chloride paint and coating removers presents "unreasonable risk." Yet, Environmental Petitioners contend, for instance, that a statement by the head of EPA's Office of Chemical Safety and Pollution Prevention that EPA had "identified significant risks to . . . workers" from using methylene chloride for paint and coating

removal, as evidence that EPA had "determined" that the commercial uses present "unreasonable risks." EP Br. at 32–33. But the Supreme Court has made clear that "the ruling of a subordinate official" is not final agency action. *Abbott Labs*, 387 U.S. at 151. Similarly, a statement in the "Scope of the Risk Evaluation for Methylene Chloride," JA__, a June 2017 document describing the conditions of use and other factors that EPA planned to assess in its methylene chloride Risk Evaluation, is not a "determination" of unreasonable risk. *See* EP Br. at 33. Any statement in the Scope document about commercial paint and coating removal could only refer to the *proposed* unreasonable risk determination found in the 2017 Proposed Rule—which, as already discussed, is not a final determination. In all respects, Environmental Petitioners' sleuthing for evidence of an unreasonable risk determination that EPA has expressly and repeatedly said was *not made* is unavailing.

EPA has proposed, under the new Section 2605(b)(4) process, to make an unreasonable risk determination for commercial use of methylene chloride for paint and coating removal. Draft Risk Evaluation at 443, JA__. EPA is subject to a statutory deadline to complete a final risk evaluation by June 2020. 15 U.S.C. § 2605(b)(4)(G). If EPA finds that commercial use of methylene chloride for paint and coating removal does *not* present an unreasonable risk, then Environmental Petitioners can seek judicial review of that determination. *See id.* §§ 2605(i)(1), 2618(a). And if EPA does find an unreasonable risk, then the statute requires EPA to propose a risk management rule within one year and promulgate a final rule within two years,

15 U.S.C. § 2605(c)(1). Environmental Petitioners will have access to judicial review both if EPA misses the statutory deadline for issuance of a risk management rule, *id.* § 2619(a), and to challenge the substance of EPA's risk determination and risk management rule once a final rule is promulgated, *id.* §§ 2605(i)(2), 2618(a)(1)(A). This is the process that Congress set out for Environmental Petitioners to raise their claims with respect to commercial paint and coating removal. They may not, however, construct a duty to act on the basis of the 2014 Risk Assessment or any other preliminary statements in the absence of any Congressional deadline or directive.[15]

Finally, EPA could not, as Environmental Petitioners suggest, finalize the Proposed Rule's risk management option for commercial paint and coating removal at the same time it issued the ANPRM. EP Br. at 44–45. Section 2605(a) directs EPA to apply restrictions "*to the extent necessary* so that the chemical substance or mixture no longer presents [unreasonable] risk." 15 U.S.C. § 2605(a) (emphasis added). Under this standard, risk management measures must be sufficient to address an identified unreasonable risk, but they cannot be more than what is "necessary" to do so. *Cf.*

[15] Before EPA promulgated the Final Rule, Environmental Petitioners sued in the U.S. District Court for the Southern District of New York, alleging that EPA had failed to perform a nondiscretionary duty when it had not taken action on the determinations and restrictions proposed in the Proposed Rule. *See Vermont Public Interest Research Grp. et al. v. Wheeler et al.*, No. 1:19-cv-2675 (S.D.N.Y.). That suit was dismissed under a voluntary stipulation on April 29, 2019. *See id.*, Order on Stipulation of Voluntary Dismissal (Dkt. 33).

EME Homer City Generation, L.P. v. EPA, 696 F.3d 7, 22 (D.C. Cir. 2012). EPA is not yet able to conclude whether the approach in the Proposed Rule as opposed to, for example, the approach outlined in the ANPRM, represents the restrictions "necessary" to address any unreasonable risk that EPA could potentially find. EPA's continuing consideration of regulatory options is reasonable and may not be subjected to judicial review.

D. Even if the lack of action on commercial paint and coating removal is reviewable, EPA reasonably explained its decision.

Even if the Court determines that EPA's inaction on commercial paint and coating removal is final and ripe for review, EPA's choice to seek additional public input rather than finalize its proposal for addressing commercial paint and coating removal was reasonable. In the Proposed Rule, EPA proposed to prohibit the use of methylene chloride for most commercial paint and coating removal; to prohibit the manufacture (including import), processing, and distribution in commerce of methylene chloride for that use; and to require downstream notification and recordkeeping. 82 Fed. Reg. 7464. EPA explained in the Final Rule that it was not finalizing the proposed unreasonable risk determination or the proposed regulation. Instead, it solicited additional comment "on questions related to a potential training, certification, and limited access program as an option for risk management for all of the commercial uses of methylene chloride in paint and coating removal." 84 Fed. Reg. at 11,421. EPA's decision to take additional comment to further inform its

regulatory action as to commercial uses, while finalizing action on consumer uses, was reasonable and within its discretion.

To begin, EPA reasonably exercised its discretion to take comment on an additional alternative risk management proposal. Neither TSCA Section 2625(*l*)(4) nor the APA imposes any requirement to finalize a proposed rule. And neither statute dictates how EPA can seek comment or otherwise prevents EPA from seeking public comment in its effort to develop risk management regulations. As explained in Part I.C.1, *supra*, TSCA does not require both consumer and commercial paint and coating removal to be regulated in the same rule or at the same time. Indeed, the Supreme Court has stated that agencies "enjoy[] broad discretion in determining how best to handle related, yet discrete, issues in terms of procedures," especially "where a different proceeding would generate more appropriate information and where the agency was addressing the question." *Mobil Oil Expl. & Producing Se. Inc. v. United Distribution Cos.*, 498 U.S. 211, 230 (1991). Here, EPA sought additional comments to help it obtain information on a number of specific questions related to a potential training, certification, and limited access program. 84 Fed. Reg. at 11,470.

Environmental Petitioners suggest that EPA's request for comment is not a genuine effort to study and pursue regulation of commercial paint and coating removal because EPA requested comment on a different certification and licensing scheme in the Proposed Rule. This ignores that the certification and licensing schemes discussed in the Proposed Rule are different from the one discussed in the ANPRM.

The Proposed Rule requested comment on a licensing regime modeled after the Lead Renovation, Repair and Painting rule. The ANPRM, by contrast, more broadly sought comment on training, certification, and limited access requirements that could address any unreasonable risks that EPA could potentially find to be presented by methylene chloride when used for commercial paint and coating removal. 84 Fed. Reg. 11,468.

Moreover, seeking more information before deciding whether and how to regulate commercial uses of methylene chloride is a perfectly good reason to defer regulatory action, particularly in the circumstances here. If EPA determines a chemical presents an unreasonable risk, it must apply risk management restriction. But it may *only* apply risk management restrictions that are "necessary" to address the risk: no more, no less. *See* 15 U.S.C. § 2605(a). Here, EPA proposed a broad prohibition on the distribution and use of methylene chloride for commercial paint and coating removal, with limited exceptions. The Department of Defense and other stakeholders urged the Agency to find a way to preserve commercial and industrial uses of methylene chloride paint and coating removers. 84 Fed. Reg. at 11,468; *see* DOD Comments at 1, JA__. EPA only received one comment directly addressing the training and certification program option described in the Proposed Rule (the Lead Renovation, Repair, and Painting Rule option). *See* 84 Fed. Reg. at 11,427–28. In light of the limited response and information it received, EPA was interested in soliciting additional public input to ensure it gave adequate consideration to the overarching training and certification program regulatory option. 84 Fed. Reg. at 11,468.

Absent any statutory or regulatory requirement, it is within "the discretion of the agencies and not that of the courts . . . [to] determin[e] when extra procedural devices should be employed." *Vt. Yankee Nuclear Power Corp. v. Nat. Res. Def. Council*, 435 U.S. 519, 543 (1978). And given that courts may only overturn an agency decision for *failing* to provide additional procedures beyond the statutory or regulatory minima in "extremely rare" circumstances, *id.* at 524, surely the circumstances in which a decision could be overturned for *providing* additional opportunity for comment are rarer still. Environmental Petitioners have not shown that such extremely rare circumstances are present here.

Finally, although EPA may determine in the future that commercial paint and coating removal presents unreasonable risks that EPA will have to address, in general, "agencies have great discretion to treat a problem partially." *City of Las Vegas v. Lujan*, 891 F.2d 927, 935 (D.C. Cir. 1989). Even if Environmental Petitioners thought the Final Rule "'should' have covered both [uses][,]" the Court should not find fault with EPA's action merely because it is only "a first step toward a complete solution"—particularly where EPA is "currently . . . address[ing]" the next steps. *Id.* at 935 & n.8; *see also Nat'l Ass'n of Broadcasters v. FCC*, 740 F.2d 1190 (D.C. Cir. 1984); *Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 471 (D.C. Cir. 1998) ("[O]rdinarily, agencies have wide latitude to attack a regulatory problem in phases[.]"). In any event, in cases where courts have declined to allow an agency to act incrementally, it has been because a step-by-step approach renders the step *taken* arbitrary or capricious, *not* the

step untaken. Here, Environmental Petitioners make no claim that the absence of a final action on commercial paint and coating removal undermines the effectiveness of the Final Rule on consumer paint and coating removal.

In sum, EPA had broad discretion both to choose to seek additional public input on an alternative regulatory approach through the ANPRM and to issue a final rule eliminating the unreasonable risk associated with consumer paint and coating removal. Environmental Petitioners' claims fail and their petitions for review should be denied.

E. A deadline is an improper remedy for Environmental Petitioners' claims.

If the Court agrees with Environmental Petitioners, EPA agrees that the proper remedy is remand without vacatur. But EPA disagrees that imposing a deadline on top of that remand, as Environmental Petitioners request, *see* EP Br. at 65, is necessary or appropriate. The only issue presented for review in Environmental Petitioners petition is whether EPA arbitrarily finalized a risk management rule on consumer use of methylene chloride paint and coating removal without also finalizing one on commercial paint and coating removal. *See* EP Br. at 65. If the Court finds error in EPA's actions, the proper remedy is remand and remand alone. *See Fed. Power Comm'n v. Idaho Power Co.*, 344 U.S. 17, 20 (1952) ("[T]he function of the reviewing court ends when an error of law is laid bare. At that point the matter once more goes to the [agency] for reconsideration.").

Imposing a deadline on top of remand would undermine the principle of administrative law that, absent "substantial justification," courts may not dictate remand's "time dimension." *Vt. Yankee*, 435 U.S. at 544–45. Neither TSCA, 15 U.S.C. § 2618, nor the APA[16] authorizes courts to direct how and when agencies respond on remand. Courts override an agency's discretion to set its own timetables "only in the most egregious cases." *Pub. Citizen Health Research Grp. v. Brock*, 823 F.2d 626, 629 (D.C. Cir. 1987) (setting deadline after agency failed to act for years despite earlier court-ordered deadline); *Envtl. Def. Fund v. EPA*, 852 F.2d 1316, 1331 (D.C. Cir. 1988).

This is not such a case. EPA promulgated the Final Rule under its discretionary Section 2625(*l*)(4) authority. 15 U.S.C. § 2625(*l*)(4). As described in Part I.C.1 *supra*, Section 2625(*l*)(4) imposes neither a requirement nor a deadline to act. Imposing a deadline as a remedy for arbitrarily or capriciously exercising this discretionary authority would thus create a duty where Congress created none.

Furthermore, nothing suggests that on remand EPA would unreasonably delay addressing commercial paint and coating removal. To the contrary, EPA is actively addressing this condition of use through the TSCA risk evaluation process, as shown by its inclusion of commercial paint and coating removal in the Draft Risk Evaluation

[16] Although review here is under 15 U.S.C. § 2618, the statute incorporates the APA by reference as the standard of review, with some exceptions.

issued in October 2019. The final risk evaluation for methylene chloride will be finalized by June 2020 and will conclude either that commercial paint and coating removal does not present an unreasonable risk or that it does, starting a statutorily prescribed rulemaking process that *is*, unlike that at issue here, subject to statutory deadlines.

If EPA does not complete the risk evaluation by the statutory deadline, Environmental Petitioners have an adequate remedy: they can bring a nondiscretionary duty suit in district court under 15 U.S.C. § 2619(a)(2). But the Court should not presume delay. "[T]he possibility of unreasonable delay in the future . . . does not justify burdening the [agency] with a court-ordered schedule for managing its docket." *In re Am. Fed. Of Gov't Employees*, 837 F.2d 503, 507 (D.C. Cir. 1988). In sum, Environmental Petitioners' requested six-month deadline to issue a decision on remand is not a proper remedy. If the Court grants Environmental Petitioners' petition, it should simply order remand.

II. HSIA's Claims

In the Final Rule, EPA concluded based on the analysis in the 2014 Risk Assessment that consumer use of methylene chloride paint and coating removers "presents an unreasonable risk of injury to health due to acute human lethality." 84 Fed. Reg. at 11,421. In light of this determination, EPA reasonably exercised its discretion under Section 2625(*l*)(4) to promulgate requirements under Section 2605(a) These ensure that consumer use of methylene chloride for paint and coating removal

"no longer presents" an unreasonable risk. In particular, EPA "prohibit[ed] the manufacture (including import), processing, and distribution in commerce of methylene chloride" for consumer paint and coating removal. 84 Fed. Reg. at 11,420. This prohibition includes the "retailer ban," whereby no "retailer" may distribute methylene chloride, including methylene chloride-containing products, for paint and coating removal. 40 C.F.R. § 751.103, 105(c); 84 Fed. Reg. at 11,435.[17]

HSIA does not contest that consumer use of methylene chloride paint and coating removers presents an "unreasonable risk." Nor does HSIA seriously contend that the proscribed prohibitions are *un*necessary to remove that risk. Rather, HSIA contends that the retailer ban is not a logical outgrowth of the proposal. HSIA also asserts the ban is arbitrary and capricious for having an incidental effect on commercial users of methylene chloride paint and coating removers and for not sufficiently taking into account certain economic factors under Section 2605(c). These arguments lack merit.

First, the Final Rule's retailer ban is a logical outgrowth of the proposal. It reasonably builds upon the consumer distribution prohibitions described in the Proposed Rule, clarifying how the prohibition would be executed. The preamble to the Proposed Rule gave HSIA ample notice of EPA's concerns with consumers' ready

[17] A "retailer" is defined as a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. 40 C.F.R. § 751.103.

access to paint and coating removers containing methylene chloride even if marketed to commercial users. EPA's path from proposal to Final Rule is rational and readily discerned. The Rule should be upheld.

Second, the policy expressed in the Final Rule meets TSCA's requirements. The restrictions in the Final Rule, including the retailer ban, are tailored to address the unreasonable risk from consumer use of methylene chloride in paint and coating removal. EPA expressed no policy with respect to commercial users. The fact that the Final Rule may have an incidental effect on commercial use is therefore not contrary to any EPA policy. Further, EPA weighed the relative costs of the adopted restriction versus the primary regulatory alternative and reasonably selected the less costly alternative.

Finally, EPA reasonably considered the Final Rule's impacts on industry. TSCA directs EPA to consider the "reasonably ascertainable economic consequences" of a Section 2605(a) restriction, based on "reasonably available information." Here, EPA reasonably estimated economic impacts where it had data to do so and explained the gaps in data where it did not. Its conclusions are supported by substantial evidence.

For these reasons and as further explained below, the Final Rule should be upheld.

A. The Final Rule is a logical outgrowth of the proposal.

Under the APA, EPA must provide notice of "either the terms or substance of the proposed rule or a description of the subjects and issues involved." 5 U.S.C.

§ 553(b)(3) (emphasis added); *see* 15 U.S.C. § 2605(c)(3) (noting that Section 553 applies to Section 2605(a) rules). Courts "have generally interpreted this to mean that the final rule the agency adopts must be 'a logical outgrowth of the rule proposed.'" *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007). In judging whether the agency has satisfied this requirement, "[t]he test . . . is whether the agency's notice would fairly apprise interested persons of the subjects and issues" of the rulemaking. *Riverkeeper, Inc. v. EPA*, 475 F.3d 83, 113 (2d Cir. 2007); *see also Cooling Water Intake Structure Coal. v. U.S. EPA*, 905 F.3d 49, 61 (2d Cir. 2018).

An agency may promulgate a rule that differs from a proposed rule. *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 175 (2007). Indeed, the very nature of the rulemaking process presumes that the nature and the specifics of the proposed rule will change as a result of comments submitted and the agency's additional analysis. *See Ass'n of Battery Recyclers, Inc. v. EPA*, 208 F.3d 1047, 1058 (D.C. Cir. 2000). Accordingly, "a final rule need not be an exact replica of the rule proposed in the Notice" and instead need only be "a 'logical outgrowth' of the rule proposed." *Nat'l Black Media Coal. v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986). *See also CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079–80 (D.C. Cir. 2009) (quotation omitted) (if "interested parties 'should have anticipated' that the change was possible, and thus reasonably should have filed their comments on the subject during the notice-and-comment period," then the rule is deemed to constitute a logical outgrowth of the proposed rule). Rather, "an agency may modify a rule through the notice-and-

comment process so long as the agency's modification is rational and 'the agency's path may reasonably be discerned.'" *Cooling Water Intake Structure Coal.*, 905 F.3d at 71 (quoting *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983)); *see also Ne. Med. Waste Disposal Auth. v. EPA*, 358 F.3d 936, 951 (D.C. Cir. 2004) ("Agencies[] are free—indeed they are encouraged—to modify proposed rules as a result of the comments they receive."). The notice requirement is thus satisfied "if affected parties should have anticipated that the relevant modification was possible," *Allina Health Servs. v. Sebelius*, 746 F.3d 1102, 1107 (D.C. Cir. 2014), or if additional notice and comment "would not provide commenters with their first occasion to offer new and different criticisms," *Fertilizer Inst. v. EPA*, 935 F.2d 1303, 1311 (D.C. Cir. 1991) (quotation marks omitted). Importantly, "the 'logical outgrowth' standard does not require the agency to assiduously lay out every detail of a proposed rule for comment." *Horsehead Res. Dev. Co.*, 16 F.3d at 1268.

Further, it is always a possible outcome, and therefore a logical outgrowth of a proposed rule, that the agency will not, in fact, adopt the rule or some portion thereof. *See, e.g., Envtl. Integrity Project v. EPA*, 425 F.3d 992, 997 (D.C. Cir. 2005) ("Of course, there is nothing objectionable in the Agency's refusal to adopt its proposed amendments . . . ."); *Am. Iron & Steel Inst. v. EPA*, 886 F.2d 390, 400 (D.C. Cir. 1989) ("One logical outgrowth of a proposal is surely, as EPA says, to refrain from taking the proposed step."). For instance, in *Arizona Public Serv. Co. v. EPA*, 211 F.3d 1280, 1299–1300 (D.C. Cir. 2000), the court found EPA's notice of proposed rulemaking

sufficient where the agency proposed that Indian tribes be required to meet the "'same requirements'" as States with respect to judicial review of Clean Air Act permitting actions, but then adopted a final rule that exempted tribes from certain, though not all, requirements.

Here, EPA's Proposed Rule "fairly apprise[d]" HSIA of the "subject and issues" of the rulemaking and the potential "terms or substance" of the rule adopted. *Nat'l Black Media Coal.*, 791 F.2d at 1022. The main changes between the proposed and the adopted rule "follow logically from" and "reasonably develop the rule[ ] proposed originally." *Conn. Light & Power Co. v. Nuclear Reg. Comm'n*, 673 F.2d 525, 532 (D.C. Cir. 1982). Further, TSCA does not subject EPA to a higher standard for what constitutes a "logical outgrowth" in Section 2605(a) rulemakings.

1. The retailer ban is a logical technical clarification that "reasonably develops" the proposed action on consumer paint and coating removal.

The retailer ban is a reasonable and foreseeable clarification of the proposed prohibition on "the manufacture (including import), processing, and distribution in commerce of methylene chloride" for consumer paint and coating removal. 82 Fed. Reg. at 7464. The Final Rule offered "[f]urther clarification" that "paint and coating removers containing methylene chloride cannot be distributed to or by retailers and clarification that a retailer includes a person that distributes in commerce or makes available a chemical substance, mixture or article to consumers, including via internet sales or distribution." 84 Fed. Reg. at 11,425. That clarification is a logical outgrowth

of the proposed prohibition on distribution for consumer paint and coating removal. Indeed, it is directly responsive and logically related to many concerns EPA expressed regarding consumer paint and coating removal restrictions in the Proposed Rule.

EPA enumerated a number of issues in designing the consumer paint and coating removal distribution prohibition that put HSIA and others on notice to submit comments about how such a prohibition should be executed. EPA noted that "[p]aint and coating removers containing methylene chloride are frequently sold at home improvement retailers or automotive supply stores that sell products to consumers as well as professional users." 82 Fed. Reg. at 7476. EPA expressed concern that because these products are widely available "on the Internet and through various additional suppliers that serve commercial and consumer customers, consumers may foreseeably purchase a variety of paint and coating removal products containing methylene chloride." 82 Fed. Reg. at 7476. Because "paint and coating removal products containing methylene chloride frequently are available in the same distribution channels to consumers and professional users," those products "cannot be straightforwardly restricted to a single type of project or user." 82 Fed. Reg. at 7479.[18] In sum, the Proposed Rule clearly highlighted EPA's concern that risk

[18] Indeed, EPA noted that an investigation into 13 deaths from methylene chloride use in bathtub refinishing, the victims used ten different products, six of which were "marketed for use in the aircraft industry, the rest for use on wood, metal, glass, and masonry." 82 Fed. Reg. at 7479. "None of the product labels mentioned bathtub refinishing." *Id.*

management would need to prevent consumer access in order to address the unreasonable risk from consumer paint and coating removal. Accordingly, "the language of the proposal contains enough suggestions of the possibility" of the retailer prohibition "to meet the test of 'adequate' notice." *United Steelworkers of Am., AFL-CIO-CLC v. Marshall*, 647 F.2d 1189, 1221–22 (D.C. Cir. 1980).

Similarly, in EPA's notes on a distribution prohibition option to address risks from consumer use of methylene chloride in paint and coating removal, *see* Regulatory Options Matrix, JA__, EPA discussed challenges to implementing such a prohibition. EPA noted that enforcement of prohibiting distribution to consumers "would be challenging as other paint removal products containing methylene chloride (intended for other uses) could be used for this purpose" because "[i]t is possible that consumers could still have access to paint removers containing methylene chloride." Regulatory Options Matrix D6, JA__. Indeed, EPA specifically noted that there would be difficulty enforcing the prohibition "unless retailers establish a mechanism for distinguishing between commercial and consumer shoppers." *Id.*

Clarifying the mechanism for preventing distribution of methylene chloride for consumer paint and coating removal became particularly relevant when EPA delayed action on commercial paint and coating removal. Although "EPA considered the impacts of regulatory options on consumer users and commercial users separately," EPA had proposed "to address paint and coating removal with methylene chloride for consumer uses together with many commercial uses, rather than as separate consumer

and commercial uses." 82 Fed. Reg. at 7479. Indeed, although EPA considered prohibiting only the "manufacturing, processing, and distribution in commerce of methylene chloride for consumer paint and coating removal," under 15 U.S.C. § 2605(a)(2), paired with downstream notification of the prohibition under 15 U.S.C. § 2605(a)(3), EPA found this would not adequately protect consumers from the proposed unreasonable risk presented by using methylene chloride for consumer paint and coating removal. 82 Fed. Reg. at 7464. EPA explained that this would not eliminate the unreasonable risk presented to consumers because "consumers can easily obtain products labeled for commercial use" because they are "readily obtainable in a variety of venues (e.g., the Internet, general retailers, and specialty stores, such as automotive stores)." *Id.*

While EPA proposed action to address risks associated with consumer and commercial uses of methylene chloride, it was "a foreseeable possibility" that EPA might choose to take action on only consumer paint and coating removal while delaying action on commercial paint and coating removal. *Idaho Conservation League v. Wheeler*, 930 F.3d 494, 508 (D.C. Cir. 2019). Taking action on one activity but not the other is a "natural subset"—and thus a logical outgrowth—of the proposal to act on both. *See La. Fed. Land Bank Ass'n v. Farm Credit Admin.*, 336 F.3d 1075, 1081 (D.C. Cir. 2003). And given EPA specifically discussed the practical problems with implementing a consumer-only distribution ban, HSIA and others had ample opportunity to comment on aspects of the rule related to preventing distribution to

consumers. Indeed, one commenter did advocate against regulation "that would prohibit retail sales of consumer-use paint strippers" containing methylene chloride. W.M. Barr Comment at 1, JA__. Because the Proposed Rule gave commenters "sufficient detail and rationale" to allow them to "participate meaningfully," *Horsehead Res. Development Co.*, 16 F.3d at 1268, the Final Rule is a logical outgrowth of the proposal and must be upheld.

Finally, the retailer prohibition is not significantly different from the proposed prohibitions on distribution for both consumer *and* most commercial uses of methylene chloride paint and coating removal products. Under the proposed rule, methylene chloride paint and coating removers could not be distributed through retailers either, with limited exceptions.[19] The retailer ban thus generally leaves commercial users in no different place than they would have been under the Proposed Rule. Instead, pending further action from EPA, they have significantly more access to methylene chloride paint and coating removers than they would have had under the Proposed Rule.

[19] Two commercial uses were not addressed by the proposed risk management restrictions: use of methylene chloride on critical corrosion-sensitive components of military aviation and vessels, which the Agency generally expected to occur through direct sales to the Department of Defense rather than through retailers, or commercial furniture stripping uses—the latter being permissible only in containers with a volume of 55 gallons or greater. 82 Fed. Reg. at 7529.

2. TSCA does not impose a more stringent "logical outgrowth" standard.

HSIA is wrong that TSCA imposes a more rigorous logical outgrowth standard than the APA. HSIA Br. at 37–39. TSCA provides only that, when proposing a Section 2605(a) risk management rule, EPA "shall . . . publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule." 15 U.S.C. § 2605(c)(3)(A). HSIA suggests that this provision "replaces" the requirement of a "general" notice of proposed rulemaking with a "particular" one. HSIA Br. at 38–39. Not so. Section 2605(c)(3) does not purport to abrogate EPA's discretion to clarify or change aspects of a rule between proposal and finality. And even if this imposes additional procedural requirements on EPA's Section 2605(a) rulemaking process, those requirements were met here.

HSIA's suggestion that cases like *Schiller v. Tower Semiconductor Ltd.*, 449 F.3d 286 (2d Cir. 2006), support its interpretation of the "particularity" provision is misleading. In *Schiller*, this court found that the Securities and Exchange Commission was not required to make certain formal findings in a specific kind of securities rulemaking beyond those required by the APA. *Schiller*, 449 F.3d at 302 (finding the Securities Act section invoked "does not mandate a statement of reasons any more detailed or specific than that required by [5 U.S.C.] § 553").[20] The Court explained in a footnote

[20] HSIA mistakenly states that *Schiller* involved a decision by the Federal Trade Commission and the statutory language of the FTC Act. As described above, *Schiller*

that "although Congress can certainly require an agency to follow procedures in addition to those mandated by the APA, Congress generally seems to do so with more specific language than that used in § 12(h)." *Id.* at 300 n.14.

Even where Congress imposes more procedural requirements, however, that does not necessarily alter the application of the logical outgrowth standard. The example of the Clean Air Act, cited by the *Schiller* court in a footnote, is instructive. Under the Clean Air Act, Congress required EPA to disclose "specific items" at the proposed rule stage and explain in the final rule "the reasons for any major changes in the promulgated rule from the proposed rule." 42 U.S.C. § 7607(d)(6)(A). Yet even with this additional procedural requirement, courts have routinely applied the normal "logical outgrowth" standard to notice-and-comment issues under the Clean Air Act. *See, e.g.*, *Ariz. Public Serv. Co.*, 211 F.3d at 1299–1300; *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 543 (D.C. Cir. 1983). TSCA's "particularity" language similarly should not affect the Court's consideration of whether the Final Rule was a logical outgrowth of the proposal.

Regardless, EPA has met any additional procedural requirement imposed by Section 2605(c)(3)(A). EPA's proposal described in great detail the "reason" for the

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involved the Securities and Exchange Commission and the Securities Act. *See Schiller*, 449 F.3d at 289. *Schiller* does cite the FTC Act as an example of a statute that imposes additional procedural requirements in addition to APA requirements, *see id.* at 300 n.14, but that footnote does not discuss the "particularity" language nor imply that such a requirement would alter the "logical outgrowth" standard.

proposed regulation: addressing any unreasonable risk presented by methylene chloride use in paint and coating removal. Black's Law Dictionary defines "reason" as "[a]n expression or statement given by way of explanation or justification; whatever is supposed or affirmed to support a conclusion, inference, or plan of action." The "reason" for a proposed rule, then, is the justification for the "plan of action": the regulatory action finalized in the Final Rule. That justification was described with "particularity" in the proposed rule. *See, e.g.*, 82 Fed. Reg. at 7465–66 (answering the question "[w]hy is the Agency taking this action?"); *id.* at 7471–72 (describing evaluation of methylene chloride risks). Furthermore, that justification remained the same in the Final Rule. *See* 84 Fed. Reg. at 11,421. EPA complied with TSCA's procedural requirements. The Court should not impose any additional requirements.

In addition to meeting the procedural requirements of TSCA, EPA's notice of proposed rulemaking also fairly apprised the public of the subject and issues of the rulemaking. The Final Rule is a "logical outgrowth" of that proposal. HSIA's claim should be rejected.

B. EPA's reasonably selected a retailer ban as necessary to remove the identified unreasonable risks to consumers.

Turning to HSIA's substantive challenges, HSIA first sets up a strawman argument that the retailer ban is arbitrary and capricious because it is inconsistent with EPA's "expressed policies" to preserve commercial uses of methylene chloride for paint coating and removal. This argument fails for several reasons. In the Final Rule,

EPA addressed consumer uses only and did not establish any policy for commercial uses. EPA reasonably determined that the retail ban was necessary to remove the unreasonable risk to consumers. And EPA appropriately accounted for any incidental effect on commercial paint and coating removal. Further, EPA reasonably rejected the primary regulatory alternative, which would have restricted sales of methylene chloride paint and coating removers to volumes 55-gallons or more for most formulations (among other requirements). EPA determined this was more costly than the retailer ban. EPA also reasonably declined to address an alternative regulatory approach, a registration and licensing scheme, because it addressed risks associated with commercial uses, which the Final Rule does not address.

1. The Final Rule sets restrictions necessary to ensure consumer paint and coating removal no longer present an unreasonable risk; EPA has not established a policy or requirements for commercial use.

EPA's Final Rule "addresses the unreasonable risk" posed by *consumer* use of methylene chloride paint and coating removers. The retailer ban accomplishes this by ensuring that methylene chloride paint and coating removers are not sold by any brick-and-mortar or e-commerce distributors that make chemical substances or mixtures available to consumer customers. The Final Rule does not address commercial paint and coating removal beyond noting that EPA "is soliciting comment, through an ANPRM published elsewhere in this issue of the Federal Register. This asks questions related to a potential training, certification, and limited

access program as an option for risk management for all of the commercial uses of methylene chloride in paint and coating removal." 84 Fed. Reg. at 11,421. EPA expressed no intention for commercial uses beyond pursuing additional comment.

HSIA contends that the retailer ban is arbitrary and capricious because it has an incidental effect on some commercial users that would typically obtain methylene chloride products from consumer retailers. *See* HSIA Br. at 21–23. HSIA's argument hinges on its belief that EPA expressed a policy preference for "allow[ing] commercial users continued access." HSIA Br. at 21. HSIA misunderstands EPA's Final Rule.

As TSCA requires, EPA selected a risk management option it determined was "necessary" to ensure that *consumer* paint and coating removal "no longer presents" the identified unreasonable risk: acute human lethality. 15 U.S.C. § 2605(a); *see* 84 Fed. Reg. at 11,423. The Final Rule accomplishes that goal: addressing unreasonable risk from consumer paint and coating removal by applying requirements that will keep methylene chloride paint and coating removal products out of consumers' hands.

The fact that commercial paint and coating removal was not regulated in the Final Rule does not show that EPA "wanted to . . . allow commercial users continued access," as HSIA claims. HSIA Br. at 21. EPA has not yet established any policy with respect to commercial paint and coating removal. *See supra* Part I.A; 84 Fed. Reg. at 11,421; 84 Fed. Reg. 11,466. Accordingly, it is not "internally inconsistent" for EPA to choose a risk management strategy for consumer paint and coating removal that has an incidental effect on commercial paint and coating removal.

Further, the fact that the retailer ban may have an incidental effect on the availability of methylene chloride for commercial paint and coating removal does not render it irrational or *ultra vires*. HSIA's suggestion that EPA cannot take action that has any effect on commercial uses without first determining that commercial uses present unreasonable risk, *see* HSIA Br. at 22, is a red herring. Section 2605(a) provides EPA discretion to take action "to the extent necessary" to address an unreasonable risk. Its regulatory options include, in some circumstances, direct regulation of the activity that presents unreasonable risk, but also regulation of activities that have a downstream effect on the unreasonable risk. Although § 2605(a) does not authorize EPA to prohibit consumer uses directly, it does authorize EPA to "prohibit[] or otherwise restrict[] the manufacture, processing, or distribution in commerce . . . for (i) *a particular use*." 15 U.S.C. § 2605(a)(2)(A). That is precisely what EPA has done.

The fact that, in addition to eliminating the unreasonable risk presented by consumer use, the retailer ban has downstream effects on commercial users does not mean EPA exceeded its authority. HSIA's argument to the contrary implies that EPA would need to make an unreasonable risk determination for any use affected by a Section 2605(a) regulation. TSCA makes no such demands. TSCA authorizes EPA to "apply one or more" "requirements" listed in Section 2605(a) "to such substance or mixture to the extent necessary so that the chemical substance or mixture no longer presents" an unreasonable risk. 15 U.S.C. § 2605(a). EPA has done that here.

HSIA also contends that EPA acted arbitrarily because the retailer ban imposes the same or greater costs as the 55-gallon restriction that was considered and rejected in the Final Rule. HSIA Br. at 26-27. HSIA reasons that because the retailers that generally sell methylene chloride paint and coating removers in less than 55-gallon containers will no longer be able to sell those products, the retailer ban amounts to a *de facto* 55-gallon volume restriction for commercial user purchases. But nothing in the record substantiates HSIA's assumption that the retailer ban imposes equal or greater costs on commercial users than the 55-gallon restriction. Nothing prevents non-retailer distributors from selling, through a different platform, the very same products (in the same volume quantities) that were previously sold through retailers. And nothing in the record shows that smaller volume direct sales to commercial users is technically or economically infeasible.

Contrary to HSIA's argument, EPA did not "overlook" this aspect of its Final Rule. Although it was not able to quantify the effects of the retail ban on commercial users, it did not ignore the potential impacts. For instance, the potential for impacts on commercial use supply chains was discussed in the Economic Analysis of the Final Rule, on which EPA relied in making its assessment of the "reasonably ascertainable economic consequences" of the rule. 84 Fed. Reg. at 11,427; *see* Economic Analysis at 4-39, JA__. In addition, EPA noted that although retailers cannot sell methylene chloride paint and coating removers, the Rule "potentially creates a new marketspace for wholesalers as they may now sell these products to commercial users who

previously purchased from retail stores." Economic Analysis at 4-39, JA__. Although currently "[w]holesalers tend not to sell products in smaller quantities, . . . with the change in the marketspace, [they] may do so if such an action would be profitable." *Id.* Indeed, HSIA acknowledges at least one commercial distributor that already sells methylene chloride paint and coating removal products in quantities under 55 gallons. HSIA Br. at 54. Thus, unlike the 55-gallon restriction, under the retail ban commercial users can continue to purchase and use methylene chloride paint and coating removers—they just have to do so from distributors that do not sell chemical substances or mixtures directly to consumers.

Regardless, the mere fact that the retailer ban may result in some costs to commercial users does not undermine the substantial evidence supporting EPA's decision. TSCA does not bar EPA from adopting regulations that impose some costs. Indeed, it may require it. When the Agency concludes that a chemical substance presents unreasonable risk, it must address that risk through Section 2605(a) risk management regulation. Congress made this obligation clear in the 2016 TSCA amendments by replacing the prior standard that Section 2605(a) rules must "protect adequately against [the unreasonable risk] *using the least burdensome requirement*" with the requirement to apply restrictions "necessary" "so that the chemical substance *no longer presents* such risk." *See* Pub. L. No. 114-182, 130 Stat. 460 (emphasis added). To be sure, assessing which restriction is "necessary" will involve some attention to economic cost. *See* 15 U.S.C. § 2605(c)(2)(A)(iv). But Congress made clear that "if no

restriction is available that the Administrator determines cost-effective in managing the risk, the identified unreasonable risk must still be addressed." H.R. Rep. No. 114-176 at 26; *see* 15 U.S.C. § 2605(a). EPA's rule should be upheld.

2. EPA reasonably rejected the primary regulatory alternative because it was more costly.

EPA's conclusion that the costs of the retailer ban adopted in the Final Rule were less than the primary regulatory alternative was reasonable and supported by substantial evidence. TSCA provides that, when selecting among regulatory options to address a chemical's unreasonable risk, EPA "shall consider . . . the reasonably ascertainable economic consequences of the rule, including . . . the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator." 15 U.S.C. § 2605(c)(2)(A)(iv)(II). The "primary alternative regulatory action" considered in the Final Rule was to prohibit the distribution in commerce of methylene chloride paint and coating removal products in containers with a volume less than 55 gallons for most formulations and to require downstream notification of the rule's requirements. *See* 84 Fed. Reg. at 11,426. EPA determined that the retailer prohibition imposed by the Final Rule was the more cost effective alternative. Although the primary alternative would have yielded even greater benefits than the retailer ban, EPA found it imposed greater burdens on processors and distributors. *Id.*; *see* Economic Analysis at 4-31, JA__. Given either alternative would decrease consumer methylene chloride use by

the same amount, *see id.* at 4-30, JA__, and would "achieve[] the necessary risk reduction for consumers and bystanders," 84 Fed. Reg. at 11,427, EPA reasonably selected the less-costly approach: the retailer ban.

EPA's decision was supported by substantial evidence. EPA's extensive Economic Analysis estimated that both the retailer ban and the 55-gallon volume limitation would have the same effect on and thus the same cost to consumers. But the 55-gallon volume limitation would have greater impacts on industry. The additional cost of the 55-gallon volume limitation was attributed to the cost of compliance with the container volume requirements which impact commercial users not targeted by the rule. 84 Fed. Reg. at 11,427. Those commercial users may not be able to acquire methylene chloride in quantities that match their needs and so would employ alternative paint and coating removal methods that EPA estimated would be more costly. *See* Economic Analysis at 4-28, JA__. In total, EPA estimated that the costs of the retailer ban would be $3.8 million to $13.6 million annualized over 20 years at a 3% discount rate and $3.8 million to $13.7 million annualized over 20 years at a 7% discount rate. 84 Fed. Reg. at 11,427. The estimated annualized costs of the primary alternative regulatory action was $5.8 million to $16.8 million at both 3% and 7% discount rates. 84 Fed. Reg. at 11,427. The Agency therefore appropriately "factored in" this cost differential, 15 U.S.C. § 2605(c)(2)(B), and selected the alternative with the lower cost.

EPA's assessment of the relative costs of the alternatives considered was reasonable and entitled to deference. EPA's assessment assumed that, under the 55-gallon limitation, commercial users who previously bought in smaller quantities would have to bear the cost of buying in larger quantities or switching to alternative methods. Under the retailer ban, by contrast, commercial users can continue to purchase in smaller quantities from non-retailers.

HSIA contends that EPA's conclusion that the retailer ban is less costly is faulty. It claims non-retail distributors do not now typically sell methylene chloride paint and coating removers in volumes smaller that 55-gallons. *See* HSIA Br. at 26–27. EPA's analysis undercuts HSIA's contention and is entitled to deference. Although EPA acknowledged that there was insufficient "reasonably available" data to make a *quantitative* assessment of the supply chain issue, *see* 15 U.S.C. § 2605(c)(2), its qualitative assessment of the issue was rational. Without volume restrictions, there is nothing preventing a new supply chain from developing. HSIA certainly does not identify any record evidence showing that EPA was unreasonable in thinking that supply chain developments will come to pass. EPA made an economically-rational, predictive judgment that, without competition from retailers, commercial distributors would supply smaller volumes of methylene chloride-containing paint and coating removers. Thus, more commercial users would be able to obtain methylene chloride-based paint and coating removers under the retailer ban than under the 55-gallon volume restriction. This rational assessment is sufficient, particularly given TSCA

requires only that EPA consider "reasonably available information" about the economic consequences of its Section 2605(a) rules. 15 U.S.C. § 2625(k). HSIA points to no such information to support its contention that EPA erred here.

In any event, HSIA's argument at most leads to the conclusion that the costs of the Final Rule are the same as the rejected 55-gallon alternative. Even assuming that the two alternatives were in equipoise with respect to cost, surely it is well within EPA's regulatory discretion to choose one over the other. As stated in a House Report addressing the 2016 TSCA amendments, Congress "does not expect EPA to analyze the cost-effectiveness of an open-ended group of possible requirements, but to focus on those that meet the subsection (a) purpose of controlling an unreasonable risk of injury." H.R. Rep. No. 114-176 at 26. EPA's action was supported by substantial evidence.

3. Neither licensing nor a training and certification program were raised as alternatives to address consumer paint and coating removal.

HSIA contends that EPA did not adequately consider two other alternatives for addressing unreasonable risk from consumer paint and coating removal: a licensing regime to differentiate consumer and commercial users and a training and certification program. But HSIA points to no comments—and EPA is aware of none—suggesting that licensing was an available regulatory alternative that could adequately address risks presented by *consumer* paint and coating removal. Moreover, given the only comment relating to licensing to address either use was received *before*

EPA published the Proposed Rule, HSIA's contention is waived. Similarly, although EPA *did* discuss a training and certification program as a way to address risks that may be presented by *commercial* paint and coating removal, it did not consider—and no commenter suggested that it should consider—that approach as a way to address the risks associated with *consumer* paint and coating removal. And nothing in the record indicates that either of these purported alternatives would meet TSCA's requirement to ensure that a chemical "no longer presents" the identified unreasonable risk. These issues are fatal to HSIA's claim.

HSIA's argument that EPA did not adequately consider a licensing regime to address the unreasonable risk presented by consumer paint and coating removal is unavailing. First, the only comment suggesting that EPA consider licensing was in a Small Business Advisory Panel conducted *before* EPA issued the Proposed Rule. HSIA identifies no comments on the actual proposal urging EPA to consider licensing to address unreasonable risk from consumer paint and coating removal. If HSIA believed that EPA wrongly overlooked that option, it needed to raise that issue in a comment on the Proposed Rule—during the official comment period—to allow EPA to give the issue meaningful consideration. Having not objected when EPA's proposal did not address licensing, HSIA cannot now contend EPA's final action was unreasonable for neglecting such a regulatory option. *See Dep't of Transp. v. Pub. Citizen*, 541 U.S. 752, 764–65 (2004) (holding a party "forfeited any objection" that the agency did not adequately consider alternatives where the issue was not raised in comments);

United States v. L.A. Tucker Truck Lines, Inc., 344 U.S. 33, 37 (1952) ("[A]s a general rule . . . courts should not topple over administrative decisions unless the [agency] not only has erred but has erred against objection made at the time appropriate under its practice.").

Second, there is no evidence in the record showing that licensing would ensure that the use of methylene chloride for consumer paint and coating removal "no longer presents" the identified unreasonable risk. Indeed, the SBAR panelist comment—which HSIA points to—only goes so far as to say that a $400 licensing fee "could *possibly* keep the average homeowner at bay." SBAR Report, JA__ (emphasis added). Indeed, given that EPA cannot regulate consumer *use* directly, *see* 15 U.S.C. § 2605(a)(5), it is unlikely that it could directly require consumer end users to obtain the sort of license roughly described by the panelist.

HSIA's argument about a training and certification regime similarly fails. In the Proposed Rule, EPA explained that it was giving "limited evaluation" to a "training and certification program for *commercial* paint and coating removers, similar to the certification process required under EPA's Lead-Based Paint Renovation, Repair, and Painting Rule," which applies to commercial workers. 82 Fed. Reg. at 7474 (citing 73 Fed. Reg. 21,692 (Apr. 22, 2008)) (emphasis added). EPA explained that it would take comment on the feasibility of this option and its potential for reducing risk "for workers." But EPA noted that a training and certification program alone would be insufficient to achieve "effective risk reduction from commercial use of methylene

chloride for paint and coating removal" without "additional regulation of distributors of these products." *Id.* EPA further explained that it "viewed the costs and challenges involved in regulating distributors and ensuring that only trained and certified commercial users are able to access these paint and coating removal products as a significant limitation for this approach." *Id.* EPA thus made clear that it was not considering the training and certification program as an option to address consumer paint and coating removal.

HSIA's argument is therefore too little, too late. HSIA had every opportunity to suggest that a training and certification program could address unreasonable risk from consumer paint and coating removal in comments on the Proposed Rule. Indeed, EPA specifically requested comment on whether a training and certification program. But neither HSIA nor any other commenter suggested such a program could address the unreasonable risk from consumer paint and coating removal. Arguments to that effect are thus waived.

EPA's treatment of the training and certification program suggestion was reasonable for two other reasons. First, EPA stated its preliminary assessment that a training and certification program would not be sufficient on its own to address the proposed unreasonable risk presented by commercial paint and coating removal. There is nothing in the record showing—and HSIA does not appear to argue—that such a program would address the unreasonable risk from consumer use to the extent required by Section 2605(a). By contrast, EPA noted that "consumers do not reliably

use personal protective equipment (respirators) or have access to engineering controls (*e.g.*, exhaust ventilation), since these methods are costly, technically challenging, and not easily available to consumers." 82 Fed. Reg. at 7477.

Second, EPA may yet adopt the sort of training, certification, and limited access program described in the ANPRM, *see* 84 Fed. Reg. at 11,425, if EPA finds an unreasonable risk from commercial paint and coating removal through the ongoing TSCA risk evaluation for methylene chloride. To the extent HSIA's challenge pertains to EPA's lack of decision on whether to adopt or reject such a scheme for commercial paint and coating removal, it fails for the same reasons described in Part I.A, *supra*. Any decision to adopt or reject any such scheme for commercial paint and coating removal will be reviewable once EPA has taken final agency action. In the absence of action, judicial review is not permitted.

In sum, EPA reasonably explained the options it considered to address consumer paint and coating removal and its decision to promulgate the retailer ban in the Final Rule was supported by substantial evidence in the record. HSIA's petition for review should therefore be denied.

C. EPA appropriately considered the "reasonably ascertainable economic consequences" of the Final Rule and its decision was supported by substantial evidence.

EPA's Final Rule was "based on a consideration of the relevant factors," *see State Farm*, 463 U.S. at 42, including assessing the reasonably ascertainable economic consequences of the rule. 15 U.S.C. § 2605(c)(2)(A). With respect to Section 2605(a)

risk management rules, the statute provides that EPA must consider costs in two principal ways. First, when deciding among risk management restrictions available under Section 2605(a), EPA must "factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a)." 15 U.S.C. § 2605(c)(2)(B). The considerations under subparagraph (A) include "the reasonably ascertainable economic consequences of the rule," *id.* § 2605(c)(2)(A)(iv). Specifically, when selecting a regulatory restriction, EPA is directed to consider:

> (I) The likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;
>
> (II) The costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and
>
> (III) The cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator

15 U.S.C. § 2605(c)(2)(A)(iv). Second, when deciding whether to prohibit or restrict a chemical substance "in a manner that substantially prevents a specific condition of use" of that chemical, EPA must "consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect." 15 U.S.C. § 2605(c)(2)(C). EPA did both here.

First, using "reasonably available information," EPA "consider[ed] and publish[ed] a statement" with respect to the "reasonably ascertainable economic consequences" of the Final Rule. 15 U.S.C. § 2605(c)(2)(A). Such consequences include, among other considerations, the costs and benefits of the regulation as well as expected effects on relevant groups such as small entities. As set out in the Final Rule's Preamble, supported by EPA's Economic Analysis of the Final Rule, JA__, EPA set out the rule's expected impacts and concluded—among other things—that the retailer ban was a less costly but equally effective way to address the unreasonable risks associated with consumer use of methylene chloride in paint and coating removal than the primary alternative. 84 Fed. Reg. at 11,426. Second, EPA assessed the availability of "technically and economically feasible alternatives." Based on EPA's discussions with "experts on and users of paint removers," as well as "industry and other governmental research," 82 Fed. Reg. at 7472, and confirmed by extensive public comment, EPA concluded that "alternatives to methylene chloride . . . are available for nearly all paint removal uses, 84 Fed. Reg. at 11,427–28.

Importantly, TSCA directs EPA to consider costs when selecting between regulatory options that ensure a chemical "no longer presents" unreasonable risks. 15 U.S.C. § 2605(c)(2)(A)(iv). Unreasonable risks may not be left unaddressed simply because there are costs associated with eliminating those risks. When promulgating a Section 2605(a) rule, EPA is required to consider and publish a statement of "the reasonably ascertainable economic consequences of the rule," including "the likely

effect of the rule on the national economy, small business, technological innovation, and public health," and a comparison of the costs and benefits and the cost effectiveness of the rule and one or more primary regulatory alternatives. 15 U.S.C. § 2605(c)(2)(A)(iv). EPA is directed to "factor in" these considerations "in selecting among prohibitions and other restrictions" available in Section 2605(a). *See id.* § 2605(c)(2)(B). But because Section 2605(a) requires EPA to apply restrictions "to the extent necessary so that the chemical substance or mixture no longer presents" unreasonable risk, the Section 2605(c)(2) considerations are secondary factors brought to bear to select among restrictions or prohibitions that will already address the risk. *See* H.R. Rep. No. 114-176 at 26 (explaining that "if no restriction is available that the Administrator determines cost-effective in managing the risk, the identified unreasonable risk must still be addressed.").

Here, EPA reasonably considered costs and benefits in the manner the 2016 TSCA amendments envisions, and appropriately selected a restriction that will eliminate the identified unreasonable risk at a lower cost than the primary regulatory alternative. Its action should be upheld.

1. EPA reasonably assessed the Final Rule's impacts on industry, using quantitative data when available and reasoned, qualitative analysis when necessary.

EPA's assessment and consideration of other costs was reasonable and supported by substantial evidence. HSIA contends that EPA failed to account for costs to retailers of lost sales of methylene chloride, costs to formulators of lost sales

to retailers, and costs to commercial users who may be unable to obtain methylene chloride substitutes from retailers. HSIA Br. at 48–53. HSIA also argues (inappropriately relying on a standing addendum rather than record evidence) that these costs are "significant" and thus leads to the conclusion that the Final Rule is not supported by substantial evidence. HSIA Br. at 53–58.

First, contrary to HSIA's argument, EPA did consider the retailer prohibition's costs to retailers, distributors, and commercial users. Although EPA excluded costs to retailers from its Economic Analysis, it did not ignore these costs. EPA noted that the impact to retailers was "uncertain" because the sales of alternative paint removers and other products "may increase, potentially offsetting some of the lost [methylene chloride] sales." Economic Analysis 2-1, JA__. "If profit margins are higher on these other products, it is possible that they could be better off under the rule." *Id.*; *see also* 84 Fed. Reg. at 11,427 (noting that the Final Rule was "likely to increase demand for chemical substitutes"). EPA further reasoned the costs to retailers were not likely to be significant "[g]iven that many retailers have announced that they are voluntarily discontinuing the sale of methylene chloride products." Economic Analysis 2-1, JA__.

Similarly, EPA considered costs to commercial end users, even if it could not quantitatively estimate the impacts. EPA acknowledged that "[s]ome commercial end users may be impacted by the Final Rule by no longer being able to purchase methylene chloride based paint and coating removal products in a normal retail store." Economic Analysis 4-39, JA__. But EPA explained that these costs were not

likely to be significant. First, EPA noted that commercial users could "switch to an alternative method of removing paint." Economic Analysis 4-39, JA__. EPA confirmed, based on extensive comment, that there are "technically and economically feasible chemical substitutes or alternative methods that are reasonably available to a consumer for almost every situation in which methylene chloride is used to remove paints or coatings." 84 Fed. Reg. at 11,427–28. If commercial users do not wish to switch suppliers, then, those "technically and economically feasible chemical substitutes" are also available to them. In addition, EPA reasoned that commercial users could obtain methylene chloride paint and coating removers from wholesalers, and that additional wholesalers may enter the market to fill demand that retailers formerly filled. Economic Analysis at 4-39. Even if EPA could not characterize impacts to commercial users quantitatively, *see id.*, this qualitative assessment is rational and unrebutted by any record evidence. Moreover, it is consistent with TSCA's standard that EPA need only consider "reasonably available information." 15 U.S.C. § 2605(c)(2). HSIA's assertion that EPA neglected costs to retailers and commercial users is baseless.

Nor did EPA neglect to consider the Final Rule's cost to distributors. Specifically, EPA reasoned that distributors—that is, "wholesaler firms distributing products containing methylene chloride"—would incur costs from the rule's downstream notification requirement. Economic Analysis at 2-4, 2-1, JA__. HSIA faults EPA for not considering the cost of lost sales of methylene chloride products

by distributors *to* retailers, but it is not clear what costs HSIA believes were left uncalculated. Distributors that are not also formulators—the impact on which was separately calculated in the Economic Analysis—only sell to retailers what they would buy from formulators. If they can no longer buy from formulators, then they are not losing any sales to retailers. Further, EPA considered the potential for unsold stock and determined that this cost would be minimal. Because the retailer ban did not go into effect until 180 days after the rule's effective date, EPA reasoned that this would "allow enough time for manufacturers, processors, *and distributors* to deplete their stocks of paint and coating removers containing methylene chloride," leaving "minimal" amounts of stranded, unsold products and thus minimal costs of lost revenue. Economic Analysis at 1-4, JA__ (emphasis added). HSIA does not address this.

Even if EPA's qualitative assessment of these costs is flawed, its determination cannot be deemed arbitrary and capricious unless it is irrational. *See Friends of Boundary Waters Wilderness v. Dombeck*, 164 F.3d 1115, 1129 (8th Cir. 1999) ("[E]ven if the agency's data is flawed," substantial deference requires the ruling be reversed only if "there is a significant chance that but for the errors the agency might have reached a different result."). The purported errors HSIA identifies do not undermine the fundamental rationale of the Final Rule: eliminating the unreasonable risk of consumer use of methylene chloride in paint and coating removal. The Court should therefore uphold EPA's action. *See N.L.R.B. v Am. Geri-Care, Inc.*, 697 F.2d 56, 64 (2d

Cir. 1982) (holding that reversal and remand are required "*only* where there is a significant chance that but for the error, the agency might have reached a different result" (emphasis in original)); *see also Envirocare of Utah, Inc. v. Nuclear Regulatory Comm'n*, 194 F.3d 72, 79 (D.C. Cir. 1999) (same).

Finally, HSIA's attempt to support its argument that EPA inadequately considered costs by pointing to a declaration in its standing addendum is improper. "It is well settled that judicial review of agency action is normally confined to the full administrative record before the agency at the time the decision was made." *Envtl. Def. Fund v. Costle*, 657 F.2d 275, 284 (1981). Although HSIA may present extra-record evidence to resolve its jurisdictional standing, it may not rely on that declaration to contend that EPA's action lacks substantial evidence under TSCA and the APA. The Court should therefore disregard HSIA's references to the standing addendum for any purpose other than demonstrating its standing—which EPA does not dispute.

2. EPA's assessment of the Final Rule's impact on methylene chloride formulators was reasonable.

HSIA also contends that EPA did not fairly evaluate costs of its final action to formulators of paint and coating removal products. HSIA Br. at 42–47. But HSIA's argument mischaracterizes the evidence presented to EPA and EPA's assessment of that evidence in the Final Rule. For instance, HSIA ignores that EPA selected the *less* costly option of the regulatory alternatives before it. Moreover, HSIA does not—and cannot—show that there was a different less costly option that would also eliminate

the identified unreasonable risk presented by consumer use of methylene chloride for paint and coating removal. In short, EPA reasonably considered costs to formulators and the ultimate regulation in the Final Rule is consistent with TSCA and supported by substantial evidence.

As part of its cost assessment, EPA estimated, based on reasonably available information, the economic costs of the Final Rule on formulators. *See* Economic Analysis at 2-2–2-3, 4-21, JA__ (discussing costs to manufacturers and processors). "EPA identified 59 different products for paint and coating removal that contain methylene chloride, formulated by 10 different firms." 84 Fed. Reg. at 11,426. EPA's estimate of the costs of the rule included "costs for manufacturers, processors, and distributors to reformulate their products and provide downstream notifications or recordkeeping." Economic Analysis xi, 4-1, JA__. EPA acknowledged that, under the Final Rule, "processors of methylene chloride containing paint and coating removal products for consumer uses will need to discontinue or reformulate those products." Economic Analysis 4-2, JA__. These reformulation costs were incorporated in EPA's estimation of "unit costs." Economic Analysis 4-2–4-3, JA__. "EPA estimate[d] reformulation costs based on reports and surveys on substances containing trichloroethylene (TCE)," settling on an average capital cost for reformulation of $27,000. Economic Analysis 4-11–4-12, JA__.

In addition to this quantitative analysis, EPA discussed qualitatively the potential impact of the Final Rule on small entity formulators. In the Final Rule's

preamble, EPA explains that it "estimates that this final rule would affect approximately 7 small entities, specifically a small number of formulators of paint and coating removal products that contain methylene chloride. The cost to these small businesses would be the cost of reformulating products sold to consumer users and the cost of complying with the downstream notification requirements." 84 Fed. Reg. at 11,433. EPA also explained that some small businesses may experience "[n]egative impacts" such as "increasing production of substitute chemicals to replace some of the production of methylene chloride," although "EPA does not expect these impacts to be costly." 84 Fed. Reg. at 11,433.

It is evident from this record that EPA did not ignore potential costs to formulators, as HSIA contends. EPA reasonably estimated quantitative costs where it could and described others qualitatively. HSIA faults EPA for extrapolating from the TCE reformulation survey. *See* HSIA Br. at 43 (citing Am. Chemistry Council Comment at 8, JA__). But EPA explained in its Response to Comments that the TCE survey "was used to augment" other information from a survey addressing the manufacturing marketspace for VOC-containing products in Canada. Response to Comments at 29–30, JA__. EPA found that the TCE survey "help[ed] confirm the appropriateness of using the Canadian study for a U.S. rulemaking analysis." *Id.* at 30. In any event, neither the Council nor any other commenter provided reasons why the TCE survey is a poor proxy, nor provided an alternative method or data source for

estimating reformulation costs. TSCA only requires EPA to consider "reasonably available information." 15 U.S.C. § 2605(c)(2)(A). EPA did so here.

HSIA overstates the costs claimed by one "small-business formulator," Charles Paint Research. HSIA Br. at 43. Charles Paint Research did not state that it would "lose 40% of its revenue." HSIA Br. at 43. Rather, it stated that 40% of its revenue "comes from methylene chloride based products." Charles Paint Research Comment at 1, JA__. The Final Rule does not prevent Charles Paint Research or others from formulating methylene chloride based products. It addresses only methylene chloride for consumer paint and coating removal. It does not follow that the consumer paint and coating removal restrictions would eliminate formulators' methylene chloride-based revenue entirely.

Similarly, HSIA's claim that the Small Business Administration's comments show that there are no reformulation options for methylene chloride is belied by the record. HSIA Br. at 43. The Small Business Administration Office of Advocacy submitted comments based on concerns raised by small business constituents. Those comments conveyed that panelists had stated a concern that "a ban on these chemicals will cause entire product lines to disappear since there are no drop-in replacements for methylene chloride." SBA Comments at 6–7. As with the Charles Paint Research comment, however, the SBA comment does not take into account that the Final Rule does *not* ban manufacturing, processing or distribution for *all* uses of methylene chloride. Formulators can continue to produce methylene chloride paint

and coating removers for commercial use. And they can continue to formulate other methylene chloride-containing products. Furthermore, the suggestion that there are no replacements for methylene chloride is contrary to the weight of evidence in the administrative record. EPA found that there are economically and technically feasible substitutes for nearly every use of methylene chloride-containing paint and coating removers. One SBA comment about does not undermine the substantial evidence that supports EPA's assessment that substitutes are, in fact, available.

In any case, EPA incorporated its reasonable assessment of formulator costs into its Section 2605 decisionmaking just as TSCA envisions. EPA identified two regulatory alternatives—(1) the selected retailer prohibition and (2) the rejected primary alternative regulatory action. As between these options, EPA rejected the regulatory alternative that would have *greater* impacts on formulators. EPA found that the primary alternative regulatory action "would introduce additional burdens to processors and distributors" and "would effectively bar most commercial users in the professional contractor, bathtub refinishing, and graffiti removal sectors given the increased cost." 84 Fed. Reg. at 11,434. EPA thus concluded that the Final Rule "is more cost effective than the primary alternative regulatory action considered." *Id.*

HSIA does not argue that EPA bypassed a less costly alternative restriction. Indeed, HSIA does not identify any alternative with less of an impact on formulators that *also* meets EPA's obligation to address unreasonable risk under Section 2605(a). In sum, EPA's assessment of the Final Rule's costs to formulators was reasonable.

HSIA's arguments do not undermine the substantial evidence that supports EPA's Final Rule.

D. Given vacatur's disruptive consequences, remand alone is a more appropriate remedy for HSIA's claims.

For all the foregoing reasons, HSIA's petition for review should be denied on the merits. But if the Court agrees with HSIA and grants any aspect of its petition for review, the Court should remand the Final Rule without vacatur. HSIA principally contends that EPA did not adequately analyze or explain the impacts of the Final Rule on various industry sectors including formulators, retailers, and commercial users. *See* HSIA Br. at 21–29, 42–58. In circumstances like those HSIA alleges, where an agency's error is rooted in "lack of reasoned decisionmaking . . . but also where the order was otherwise arbitrary or capricious," courts have "commonly" remanded without vacatur. *Int'l Union UMW v. FMSHA*, 920 F.2d 960, 966–67 (D.C. Cir. 1990); *see Allied-Signal, Inc. v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 150 (2d Cir. 1993) ("An inadequately supported rule . . . need not necessarily be vacated."). "The decision whether to vacate depends on 'the seriousness of the order's deficiencies (and thus the extent of doubt whether the agency chose correctly) and the disruptive consequences of an interim change that may itself be changed." *Id.* at 150–51 (quoting *Int'l Union*, 920 F.2d at 966–67).

Neither condition is met here. First, vacatur would have disruptive consequences both for industry, which has begun complying with the retailer

prohibitions, and especially for consumers, who would once again be exposed to unreasonable risk. Second, the purported violations described in HSIA's brief are not "serious" enough to warrant vacatur.

Vacatur would impose more hardship than it would avoid. Vacatur could very well put methylene chloride paint and coating removers back on retail shelves where consumers have ready access to them. EPA determined that consumer use of methylene chloride paint and coating removers presents an unreasonable risk of injury to health due to acute human lethality. HSIA does not dispute that determination. Ready access could lead to ready use, as TSCA does not allow EPA to directly regulate consumer use. *See* 15 U.S.C. § 2605(a). Without the Final Rule or any substitute, the undisputed unreasonable risk would resume, putting consumers at risk.

By contrast, the costs of retaining the Final Rule through remand are negligible. EPA determined—supported by extensive comments—that there are technically and economically feasible substitutes for nearly every paint and coating remover use affected by the rule. *See* 84 Fed. Reg. at 11,427–28. Indeed, the fact that many retailers have stated a commitment to voluntarily stop carrying methylene chloride paint and coating removers is evidence that the harm of retaining the retailer distribution prohibition is small. *See* Economic Analysis; Final Rule.

HSIA downplays vacatur's costs by suggesting that the ban on distribution of methylene chloride for consumer paint and coating removal can remain in effect even as the retailer provision is vacated. But HSIA does not explain how the consumer

distribution ban would be effectively executed or enforced absent the retailer ban. The retailer provisions of the consumer distribution ban were put into place precisely to eliminate access to methylene chloride for consumer paint and coating removal. EPA found—and HSIA does not dispute—that "consumers can easily use paint removal products intended for or marketed to professional users since paint removal products are readily available at many big box, local hardware, and paint specialty stores." 84 Fed. Reg. at 11,426; *see also id.* ("Products intended for one specific type of paint removal project can be easily used in a different setting, including by consumers or hobbyists."). Merely stating that distribution to consumers is prohibited does not ensure that the unreasonable risk of consumer use is addressed. And a ban without structured implementation creates more uncertainty for the regulated community. Given, then, that "the consequences of vacating may be quite disruptive," the Court should decline to vacate here. *Allied-Signal*, 988 F.2d at 151.

To the extent the Court agrees with HSIA that EPA did not take into account certain costs, EPA can do that on remand. There is no reason to think that a consideration of those costs would change the agency's action. Indeed, HSIA has not shown that any less costly alternative ensures that consumer paint and coating removal products no longer present an unreasonable risk of injury to health. *See Int'l Union*, 920 F.2d at 967 ("As the record affords us no basis for concluding that the deficiencies of the order will prove substantially fatal, we remand the case but do not vacate."). In any event, to the extent those considerations do warrant a change in

EPA's action, that change should be made by the EPA so that it may promulgate a replacement that will adequately ensure that the undisputed unreasonable risk is no longer presented.

HSIA's claims should be denied. But if the Court grants HSIA's petition for review, remand without vacatur is the appropriate remedy.

CONCLUSION

For the foregoing reasons, the petitions for review should be denied.

Respectfully submitted,

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January 31, 2020

CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limit set out in the Court's October 2, 2019 order (Dkt. 113) because it contains 25,257 words. This brief also complies with the typeface and type-style requirements of Federal Rule of Appellate Procedure 32(a)(5)–(6) because it was prepared using Microsoft Word 2016 in Garamond 14-point font, a proportionally spaced typeface.

s/ Sarah A. Buckley
SARAH A. BUCKLEY

CERTIFICATE OF SERVICE

I hereby certify that on January 31, 2020, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system. Participants in the case are registered CM/ECF users, and service will be accomplished by the appellate CM/ECF system.

s/ Sarah A. Buckley
Sarah A. Buckley

ADDENDUM

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5 U.S.C.A. § 553

§ 553. Rule making

Currentness

(a) This section applies, according to the provisions thereof, except to the extent that there is involved--

(1) a military or foreign affairs function of the United States; or

(2) a matter relating to agency management or personnel or to public property, loans, grants, benefits, or contracts.

(b) General notice of proposed rule making shall be published in the Federal Register, unless persons subject thereto are named and either personally served or otherwise have actual notice thereof in accordance with law. The notice shall include--

(1) a statement of the time, place, and nature of public rule making proceedings;

(2) reference to the legal authority under which the rule is proposed; and

(3) either the terms or substance of the proposed rule or a description of the subjects and issues involved.

Except when notice or hearing is required by statute, this subsection does not apply--

(A) to interpretative rules, general statements of policy, or rules of agency organization, procedure, or practice; or

(B) when the agency for good cause finds (and incorporates the finding and a brief statement of reasons therefor in the rules issued) that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest.

(c) After notice required by this section, the agency shall give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments with or without opportunity for oral presentation. After consideration of the relevant matter presented, the agency shall incorporate in the rules adopted a concise general statement of their basis and purpose. When rules are required by statute to be made on the record after opportunity for an agency hearing, sections 556 and 557 of this title apply instead of this subsection.

(d) The required publication or service of a substantive rule shall be made not less than 30 days before its effective date, except--

(1) a substantive rule which grants or recognizes an exemption or relieves a restriction;

(2) interpretative rules and statements of policy; or

(3) as otherwise provided by the agency for good cause found and published with the rule.

(e) Each agency shall give an interested person the right to petition for the issuance, amendment, or repeal of a rule.

CREDIT(S)

(Pub.L. 89-554, Sept. 6, 1966, 80 Stat. 383.)

EXECUTIVE ORDERS

EXECUTIVE ORDER NO. 12044

Ex. Ord. No. 12044, Mar. 23, 1978, 43 F.R. 12661, as amended by Ex. Ord. No. 12221, June 27, 1980, 45 F.R. 44249, which related to the improvement of Federal regulations, was revoked by Ex. Ord. No. 12291, Feb. 17, 1981, 46 F.R. 13193, formerly set out as a note under section 601 of this title.

Notes of Decisions (1438)

5 U.S.C.A. § 553, 5 USCA § 553
Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

KeyCite Yellow Flag - Negative Treatment
Proposed Legislation

United States Code Annotated Title 15. Commerce and Trade Chapter 53. Toxic Substances Control (Refs & Annos) Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2603

§ 2603. Testing of chemical substances and mixtures

Effective: June 22, 2016
Currentness

(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 (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.

(5) Repealed. Pub.L. 114-182, Title I, § 4(3)(E), June 22, 2016, 130 Stat. 451

(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 preceeding [1] 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 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.

(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.

(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 substance 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.

ADD13

(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).

CREDIT(S)

(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.)

Notes of Decisions (8)

Footnotes

1 So in original. Probably should be “preceding”.

15 U.S.C.A. § 2603, 15 USCA § 2603

Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

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 data 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) of this section to submit such data, 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 data 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 data 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 data,

whichever is later.

(3) The requirements of subsections (a) and (b) of this section 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. 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.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) of this section 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

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

(Pub. L. 94-469, § 5, Oct. 11, 1976, 90 Stat. 2012.)

SECTION REFERRED TO IN OTHER SECTIONS

This section is referred to in sections 2603, 2606, 2607, 2611 to 2613, 2614, 2616 to 2620, 2623, 2625, 2630 of this title.

§ 2605. Regulation of hazardous chemical substances and mixtures

(a) Scope of regulation

If the Administrator finds that there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, presents or will present an unreasonable risk of injury to health or the environment, the Administrator shall by rule apply one or more of the following requirements to such substance or mixture to the extent necessary to protect adequately against such risk using the least burdensome requirements:

(1) A requirement (A) prohibiting 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 the manufacture, processing, or distribution in commerce of such substance or mixture for (i) a particular use

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Proposed Legislation

United States Code Annotated Title 15. Commerce and Trade Chapter 53. Toxic Substances Control (Refs & Annos) Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2605

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

Effective: June 22, 2016
Currentness

(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 disposal 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.

(ii) Low-priority substances

The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.

(C) Information request and review and proposed and final prioritization designation

The rulemaking required in subparagraph (A) shall ensure that the time required to make a priority designation of a chemical substance be no shorter than nine months and no longer than 1 year, and that the process for such designations includes--

(i) a requirement that the Administrator request interested persons to submit relevant information on a chemical substance that the Administrator has initiated the prioritization process on, before proposing a priority designation for the chemical substance, and provide 90 days for such information to be provided;

(ii) a requirement that the Administrator publish each proposed designation of a chemical substance as a high- or low-priority substance, along with an identification of the information, analysis, and basis used to make the proposed designations, and provide 90 days for public comment on each such proposed designation; and

(iii) a process by which the Administrator may extend the deadline in clause (i) for up to three months in order to receive or evaluate information required to be submitted in accordance with section 2603(a)(2)(B) of this title, subject to the limitation that if the information available to the Administrator at the end of such an extension remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.

(2) Initial risk evaluations and subsequent designations of high- and low-priority substances

(A) Initial risk evaluations

Not later than 180 days after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on 10 chemical substances drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments and shall publish the list of such chemical substances during the 180 day period.

(B) Additional risk evaluations

Not later than three and one half years after June 22, 2016, the Administrator shall ensure that risk evaluations are being conducted on at least 20 high-priority substances and that at least 20 chemical substances have been designated as low-priority substances, subject to the limitation that at least 50 percent of all chemical substances on which risk evaluations are being conducted by the Administrator are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments.

(C) Continuing designations and risk evaluations

The Administrator shall continue to designate priority substances and conduct risk evaluations in accordance with this subsection at a pace consistent with the ability of the Administrator to complete risk evaluations in accordance with the deadlines under paragraph (4)(G).

(D) Preference

In designating high-priority substances, the Administrator shall 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.

(E) Metals and metal compounds

In identifying priorities for risk evaluation and conducting risk evaluations of metals and metal compounds, the Administrator shall use the Framework for Metals Risk Assessment of the Office of the Science Advisor, Risk Assessment Forum, and dated March 2007, or a successor document that addresses metals risk assessment and is peer reviewed by the Science Advisory Board.

(3) Initiation of risk evaluations; designations

(A) Risk evaluation initiation

Upon designating a chemical substance as a high-priority substance, the Administrator shall initiate a risk evaluation on the substance.

(B) Revision

The Administrator may revise the designation of a low-priority substance based on information made available to the Administrator.

(C) Ongoing designations

The Administrator shall designate at least one high-priority substance upon the completion of each risk evaluation (other than risk evaluations for chemical substances designated under paragraph (4)(C)(ii)).

(4) Risk evaluation process and deadlines

(A) In general

The Administrator shall conduct risk evaluations pursuant to this paragraph to determine whether a chemical substance presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant to the risk evaluation by the Administrator, under the conditions of use.

(B) Establishment of process

Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a process to conduct risk evaluations in accordance with subparagraph (A).

(C) Requirement

The Administrator shall conduct and publish risk evaluations, in accordance with the rule promulgated under subparagraph (B), for a chemical substance--

(i) that has been identified under paragraph (2)(A) or designated under paragraph (1)(B)(i); and

(ii) subject to subparagraph (E), that a manufacturer of the chemical substance has requested, in a form and manner and using the criteria prescribed by the Administrator in the rule promulgated under subparagraph (B), be subjected to a risk evaluation.

(D) Scope

The Administrator shall, not later than 6 months after the initiation of a risk evaluation, 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 consider, and, for each designation of a high-priority substance, ensure not less than 12 months between the initiation of the prioritization process for the chemical substance and the publication of the scope of the risk evaluation for the chemical substance, and for risk evaluations conducted on chemical substances that have been identified under paragraph (2)(A) or selected under subparagraph (E)(iv)(II) of this paragraph, ensure not less than 3 months before the Administrator publishes the scope of the risk evaluation.

(E) Limitation and criteria

(i) Percentage requirements

The Administrator shall ensure that, of the number of chemical substances that undergo a risk evaluation under clause (i) of subparagraph (C), the number of chemical substances undergoing a risk evaluation under clause (ii) of subparagraph (C) is--

(I) not less than 25 percent, if sufficient requests are made under clause (ii) of subparagraph (C); and

(II) not more than 50 percent.

(ii) Requested risk evaluations

Requests for risk evaluations under subparagraph (C)(ii) shall be subject to the payment of fees pursuant to section 2625(b) of this title, and the Administrator shall not expedite or otherwise provide special treatment to such risk evaluations.

(iii) Preference

In deciding whether to grant requests under subparagraph (C)(ii), the Administrator shall give preference to requests for risk evaluations on chemical substances for which the Administrator determines that restrictions imposed by 1 or more States have the potential to have a significant impact on interstate commerce or health or the environment.

(iv) Exceptions

(I) Chemical substances for which requests have been granted under subparagraph (C)(ii) shall not be subject to section 2617(b) of this title.

(II) Requests for risk evaluations on chemical substances which are made under subparagraph (C)(ii) and that are drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments shall be granted at the discretion of the Administrator and not be subject to clause (i)(II).

(F) Requirements

In conducting a risk evaluation under this subsection, the Administrator shall--

(i) integrate and assess available information on hazards and exposures for the conditions of use of the chemical substance, including information that is relevant to specific risks of injury to health or the environment and information on potentially exposed or susceptible subpopulations identified as relevant by the Administrator;

(ii) describe whether aggregate or sentinel exposures to a chemical substance under the conditions of use were considered, and the basis for that consideration;

(iii) not consider costs or other nonrisk factors;

(iv) take into account, where relevant, the likely duration, intensity, frequency, and number of exposures under the conditions of use of the chemical substance; and

(v) describe the weight of the scientific evidence for the identified hazard and exposure.

(G) Deadlines

The Administrator--

(i) shall complete a risk evaluation for a chemical substance as soon as practicable, but not later than 3 years after the date on which the Administrator initiates the risk evaluation under subparagraph (C); and

(ii) may extend the deadline for a risk evaluation for not more than 6 months.

(H) Notice and comment

The Administrator shall provide no less than 30 days public notice and an opportunity for comment on a draft risk evaluation prior to publishing a final risk evaluation.

(c) Promulgation of subsection (a) rules

(1) Deadlines

If the Administrator determines that a chemical substance presents an unreasonable risk of injury to health or the environment in accordance with subsection (b)(4)(A), the Administrator--

(A) shall propose in the Federal Register a rule under subsection (a) for the chemical substance not later than 1 year after the date on which the final risk evaluation regarding the chemical substance is published;

(B) shall publish in the Federal Register a final rule not later than 2 years after the date on which the final risk evaluation regarding the chemical substance is published; and

(C) may extend the deadlines under this paragraph for not more than 2 years, subject to the condition that the aggregate length of extensions under this subparagraph and subsection (b)(4)(G)(ii) does not exceed 2 years, and subject to the limitation that the Administrator may not extend a deadline for the publication of a proposed or final rule regarding a chemical substance drawn from the 2014 update of the TSCA Work Plan for Chemical Assessments or a chemical substance that, with respect to persistence and bioaccumulation, scores high for 1 and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), without adequate public justification that demonstrates, following a review of the information reasonably available to the Administrator, that the Administrator cannot complete the proposed or final rule without additional information regarding the chemical substance.

(2) Requirements for rule

(A) Statement of effects

In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to--

(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

(iii) the benefits of the chemical substance or mixture for various uses; and

(iv) the reasonably ascertainable economic consequences of the rule, including consideration of--

(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

(B) Selecting requirements

In selecting among prohibitions and other restrictions, the Administrator shall factor in, to the extent practicable, the considerations under subparagraph (A) in accordance with subsection (a).

(C) Consideration of alternatives

Based on the information published under subparagraph (A), in deciding whether to prohibit or restrict in a manner that substantially prevents a specific condition of use of a chemical substance or mixture, and in setting an appropriate transition period for such action, the Administrator shall consider, to the extent practicable, whether technically and economically feasible alternatives that benefit health or the environment, compared to the use so proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or other restriction takes effect.

(D) Replacement parts

(i) In general

The Administrator shall exempt replacement parts for complex durable goods and complex consumer goods that are designed prior to the date of publication in the Federal Register of the rule under subsection (a), unless the Administrator finds that such replacement parts contribute significantly to the risk, identified in a risk evaluation conducted under subsection (b)(4)(A), to the general population or to an identified potentially exposed or susceptible subpopulation.

(ii) Definitions

In this subparagraph--

(I) the term "complex consumer goods" means electronic or mechanical devices composed of multiple manufactured components, with an intended useful life of 3 or more years, where the product is typically not consumed, destroyed, or discarded after a single use, and the components of which would be impracticable to redesign or replace; and

(II) the term "complex durable goods" means manufactured goods composed of 100 or more manufactured components, with an intended useful life of 5 or more years, where the product is typically not consumed, destroyed, or discarded after a single use.

(E) Articles

In selecting among prohibitions and other restrictions, the Administrator shall apply such prohibitions or other restrictions to an article or category of articles containing the chemical substance or mixture only to the extent necessary to address the identified risks from exposure to the chemical substance or mixture from the article or category of articles so that the substance or mixture does not present an unreasonable risk of injury to health or the environment identified in the risk evaluation conducted in accordance with subsection (b)(4)(A).

(3) Procedures

When prescribing a rule under subsection (a) the Administrator shall proceed in accordance with section 553 of Title 5 (without regard to any reference in such section to sections 556 and 557 of such title), and shall also--

(A) publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule;

(B) allow interested persons to submit written data, views, and arguments, and make all such submissions publicly available;

(C) promulgate a final rule based on the matter in the rulemaking record; and

(D) make and publish with the rule the determination described in subsection (a).

(d) Effective date

(1) In general

In any rule under subsection (a), the Administrator shall--

(A) specify the date on which it shall take effect, which date shall be as soon as practicable;

(B) except as provided in subparagraphs (C) and (D), specify mandatory compliance dates for all of the requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in a case of a use exempted under subsection (g);

(C) specify mandatory compliance dates for the start of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable, but not later than 5 years after the date of promulgation of the rule, except in the case of a use exempted under subsection (g);

(D) specify mandatory compliance dates for full implementation of ban or phase-out requirements under a rule under subsection (a), which shall be as soon as practicable; and

(E) provide for a reasonable transition period.

(2) Variability

As determined by the Administrator, the compliance dates established under paragraph (1) may vary for different affected persons.

(3)(A) The Administrator may declare a proposed rule under subsection (a) to be effective, and compliance with the proposed requirements to be mandatory, upon publication in the Federal Register of the proposed rule and until the compliance dates applicable to such requirements in a final rule promulgated under section 2605(a) of this title or until the Administrator revokes such proposed rule, in accordance with subparagraph (B), if--

(i) the Administrator determines that--

(I) the manufacture, processing, distribution in commerce, use, or disposal of the chemical substance or mixture subject to such proposed rule or any combination of such activities is likely to result in an unreasonable risk of serious or widespread injury to health or the environment before such effective date without consideration of costs or other non-risk factors; and

(II) making such proposed rule so effective is necessary to protect the public interest; and

(ii) in the case of a proposed rule to prohibit the manufacture, processing, or distribution of a chemical substance or mixture because of the risk determined under clause (i)(I), a court has in an action under section 2606 of this title granted relief with respect to such risk associated with such substance or mixture.

Such a proposed rule which is made so effective shall not, for purposes of judicial review, be considered final agency action.

(B) If the Administrator makes a proposed rule effective upon its publication in the Federal Register, the Administrator shall, as expeditiously as possible, give interested persons prompt notice of such action in accordance with subsection (c), and either promulgate such rule (as proposed or with modifications) or revoke it.

(e) Polychlorinated biphenyls

(1) Within six months after January 1, 1977, the Administrator shall promulgate rules to--

(A) prescribe methods for the disposal of polychlorinated biphenyls, and

(B) require polychlorinated biphenyls to be marked with clear and adequate warnings, and instructions with respect to their processing, distribution in commerce, use, or disposal or with respect to any combination of such activities.

Requirements prescribed by rules under this paragraph shall be consistent with the requirements of paragraphs (2) and (3).

(2)(A) Except as provided under subparagraph (B), effective one year after January 1, 1977, no person may manufacture, process, or distribute in commerce or use any polychlorinated biphenyl in any manner other than in a totally enclosed manner.

(B) The Administrator may by rule authorize the manufacture, processing, distribution in commerce or use (or any combination of such activities) of any polychlorinated biphenyl in a manner other than in a totally enclosed manner if the Administrator finds that such manufacture, processing, distribution in commerce, or use (or combination of such activities) will not present an unreasonable risk of injury to health or the environment.

(C) For the purposes of this paragraph, the term "totally enclosed manner" means any manner which will ensure that any exposure of human beings or the environment to a polychlorinated biphenyl will be insignificant as determined by the Administrator by rule.

(3)(A) Except as provided in subparagraphs (B) and (C)--

(i) no person may manufacture any polychlorinated biphenyl after two years after January 1, 1977, and

(ii) no person may process or distribute in commerce any polychlorinated biphenyl after two and one-half years after such date.

(B) Any person may petition the Administrator for an exemption from the requirements of subparagraph (A), and the Administrator may grant by rule such an exemption if the Administrator finds that--

(i) an unreasonable risk of injury to health or environment would not result, and

(ii) good faith efforts have been made to develop a chemical substance which does not present an unreasonable risk of injury to health or the environment and which may be substituted for such polychlorinated biphenyl.

An exemption granted under this subparagraph shall be subject to such terms and conditions as the Administrator may prescribe and shall be in effect for such period (but not more than one year from the date it is granted) as the Administrator may prescribe.

(C) Subparagraph (A) shall not apply to the distribution in commerce of any polychlorinated biphenyl if such polychlorinated biphenyl was sold for purposes other than resale before two and one half years after October 11, 1976.

(D) Omitted

(4) Any rule under paragraph (1), (2)(B), or (3)(B) shall be promulgated in accordance with paragraph (3) of subsection (c).

(5) This subsection does not limit the authority of the Administrator, under any other provision of this chapter or any other Federal law, to take action respecting any polychlorinated biphenyl.

(f) Mercury

(1) Prohibition on sale, distribution, or transfer of elemental mercury by Federal agencies

Except as provided in paragraph (2), effective beginning on October 14, 2008, no Federal agency shall convey, sell, or distribute to any other Federal agency, any State or local government agency, or any private individual or entity any elemental mercury under the control or jurisdiction of the Federal agency.

(2) Exceptions

Paragraph (1) shall not apply to--

(A) a transfer between Federal agencies of elemental mercury for the sole purpose of facilitating storage of mercury to carry out this chapter; or

(B) a conveyance, sale, distribution, or transfer of coal.

(3) Leases of Federal coal

Nothing in this subsection prohibits the leasing of coal.

(g) Exemptions

(1) Criteria for exemption

The Administrator may, as part of a rule promulgated under subsection (a), or in a separate rule, grant an exemption from a requirement of a subsection (a) rule for a specific condition of use of a chemical substance or mixture, if the Administrator finds that--

(A) the specific condition of use is a critical or essential use for which no technically and economically feasible safer alternative is available, taking into consideration hazard and exposure;

(B) compliance with the requirement, as applied with respect to the specific condition of use, would significantly disrupt the national economy, national security, or critical infrastructure; or

(C) the specific condition of use of the chemical substance or mixture, as compared to reasonably available alternatives, provides a substantial benefit to health, the environment, or public safety.

(2) Exemption analysis and statement

In proposing an exemption under this subsection, the Administrator shall analyze the need for the exemption, and shall make public the analysis and a statement describing how the analysis was taken into account.

(3) Period of exemption

The Administrator shall establish, as part of a rule under this subsection, a time limit on any exemption for a time to be determined by the Administrator as reasonable on a case-by-case basis, and, by rule, may extend, modify, or eliminate an exemption if the Administrator determines, on the basis of reasonably available information and after adequate public justification, the exemption warrants extension or modification or is no longer necessary.

(4) Conditions

As part of a rule promulgated under this subsection, the Administrator shall include conditions, including reasonable recordkeeping, monitoring, and reporting requirements, to the extent that the Administrator determines the conditions are necessary to protect health and the environment while achieving the purposes of the exemption.

(h) Chemicals that are persistent, bioaccumulative, and toxic

(1) Expedited action

Not later than 3 years after June 22, 2016, the Administrator shall propose rules under subsection (a) with respect to chemical substances identified in the 2014 update of the TSCA Work Plan for Chemical Assessments--

(A) that the Administrator has a reasonable basis to conclude are toxic and that with respect to persistence and bioaccumulation score high for one and either high or moderate for the other, pursuant to the TSCA Work Plan Chemicals Methods Document published by the Administrator in February 2012 (or a successor scoring system), and are not a metal or a metal compound, and for which the Administrator has not completed a Work Plan Problem Formulation, initiated a

review under section 2604 of this title, or entered into a consent agreement under section 2603 of this title, prior to June 22, 2016; and

(B) exposure to which under the conditions of use is likely to the general population or to a potentially exposed or susceptible subpopulation identified by the Administrator, or the environment, on the basis of an exposure and use assessment conducted by the Administrator.

(2) No risk evaluation required

The Administrator shall not be required to conduct risk evaluations on chemical substances that are subject to paragraph (1).

(3) Final rule

Not later than 18 months after proposing a rule pursuant to paragraph (1), the Administrator shall promulgate a final rule under subsection (a).

(4) Selecting restrictions

In selecting among prohibitions and other restrictions promulgated in a rule under subsection (a) pursuant to paragraph (1), the Administrator shall address the risks of injury to health or the environment that the Administrator determines are presented by the chemical substance and shall reduce exposure to the substance to the extent practicable.

(5) Relationship to subsection (b)

If, at any time prior to the date that is 90 days after June 22, 2016, the Administrator makes a designation under subsection (b)(1)(B)(i), or receives a request under subsection (b)(4)(C)(ii), such chemical substance shall not be subject to this subsection, except that in selecting among prohibitions and other restrictions promulgated in a rule pursuant to subsection (a), the Administrator shall both ensure that the chemical substance meets the rulemaking standard under subsection (a) and reduce exposure to the substance to the extent practicable.

(i) Final agency action

Under this section and subject to section 2617 of this title--

(1) a determination by the Administrator under subsection (b)(4)(A) that a chemical substance does not present an unreasonable risk of injury to health or the environment shall be issued by order and considered to be a final agency action, effective beginning on the date of issuance of the order; and

(2) a final rule promulgated under subsection (a), including the associated determination by the Administrator under subsection (b)(4)(A) that a chemical substance presents an unreasonable risk of injury to health or the environment, shall be considered to be a final agency action, effective beginning on the date of promulgation of the final rule.

(j) Definition

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

CREDIT(S)

(Pub.L. 94-469, Title I, § 6, Oct. 11, 1976, 90 Stat. 2020; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 109-364, Div. A, Title III, § 317(a), Oct. 17, 2006, 120 Stat. 2142; Pub.L. 110-414, § 3, Oct. 14, 2008, 122 Stat. 4342; Pub.L. 114-182, Title I, § 6, June 22, 2016, 130 Stat. 460.)

Notes of Decisions (37)

15 U.S.C.A. § 2605, 15 USCA § 2605
Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

United States Code Annotated Title 15. Commerce and Trade Chapter 53. Toxic Substances Control (Refs & Annos) Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2619

§ 2619. Citizens' civil actions

Effective: June 22, 2016
Currentness

(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 United States district court for the judicial district in which the plaintiff is domiciled. The district courts of the United States shall have jurisdiction over suits brought under this section, without regard to the amount in controversy or the citizenship of the parties. In any civil action under this subsection process may be served on a defendant in any judicial district in which the defendant resides or may be found and subpoenas for witnesses may be served in any judicial district.

(b) Limitation

No civil action may be commenced--

(1) under subsection (a)(1) to restrain a violation of this chapter or rule or order under this chapter--

(A) before the expiration of 60 days after the plaintiff has given notice of such violation (i) to the Administrator, and (ii) to the person who is alleged to have committed such violation, or

(B) if the Administrator has commenced and is diligently prosecuting a proceeding for the issuance of an order under section 2615(a)(2) of this title to require compliance with this chapter or with such rule or order or if the Attorney General has commenced and is diligently prosecuting a civil action in a court of the United States to require compliance with this

chapter or with such rule or order, but if such proceeding or civil action is commenced after the giving of notice, any person giving such notice may intervene as a matter of right in such proceeding or action;

(2) under subsection (a)(2) before the expiration of 60 days after the plaintiff has given notice to the Administrator of the alleged failure of the Administrator to perform an act or duty which is the basis for such action or, in the case of an action under such subsection for the failure of the Administrator to file an action under section 2606 of this title, before the expiration of ten days after such notification, except that no prior notification shall be required in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title; or

(3) in the case of a civil action brought to compel a decision by the Administrator pursuant to section 2617(f)(3)(B) of this title, after the date that is 60 days after the deadline specified in section 2617(f)(3)(B) of this title.

Notice under this subsection shall be given in such manner as the Administrator shall prescribe by rule.

(c) General

(1) In any action under this section, the Administrator, if not a party, may intervene as a matter of right.

(2) The court, in issuing any final order in any action brought pursuant to subsection (a), may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(3) Nothing in this section shall restrict any right which any person (or class of persons) may have under any statute or common law to seek enforcement of this chapter or any rule or order under this chapter or to seek any other relief.

(d) Consolidation

When two or more civil actions brought under subsection (a) involving the same defendant and the same issues or violations are pending in two or more judicial districts, such pending actions, upon application of such defendants to such actions which is made to a court in which any such action is brought, may, if such court in its discretion so decides, be consolidated for trial by order (issued after giving all parties reasonable notice and opportunity to be heard) of such court and tried in--

(1) any district which is selected by such defendant and in which one of such actions is pending,

(2) a district which is agreed upon by stipulation between all the parties to such actions and in which one of such actions is pending, or

(3) a district which is selected by the court and in which one of such actions is pending.

The court issuing such an order shall give prompt notification of the order to the other courts in which the civil actions consolidated under the order are pending.

United States Code Annotated Title 15. Commerce and Trade Chapter 53. Toxic Substances Control (Refs & Annos) Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2620

§ 2620. Citizens' petitions

Effective: June 22, 2016
Currentness

(a) In general

Any person may petition the Administrator to initiate a proceeding for the issuance, amendment, or repeal of a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title.

(b) Procedures

(1) Such petition shall be filed in the principal office of the Administrator and shall set forth the facts which it is claimed establish that it is necessary to issue, amend, or repeal a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title.

(2) The Administrator may hold a public hearing or may conduct such investigation or proceeding as the Administrator deems appropriate in order to determine whether or not such petition should be granted.

(3) Within 90 days after filing of a petition described in paragraph (1), the Administrator shall either grant or deny the petition. If the Administrator grants such petition, the Administrator shall promptly commence an appropriate proceeding in accordance with section 2603, 2604, 2605, or 2607 of this title. If the Administrator denies such petition, the Administrator shall publish in the Federal Register the Administrator's reasons for such denial.

(4)(A) If the Administrator denies a petition filed under this section (or if the Administrator fails to grant or deny such petition within the 90-day period) the petitioner may commence a civil action in a district court of the United States to compel the Administrator to initiate a rulemaking proceeding as requested in the petition. Any such action shall be filed within 60 days after the Administrator's denial of the petition or, if the Administrator fails to grant or deny the petition within 90 days after filing the petition, within 60 days after the expiration of the 90-day period.

(B) In an action under subparagraph (A) respecting a petition to initiate a proceeding to issue a rule under section 2603, 2605, or 2607 of this title or an order under section 2603 or 2604(e) or (f) of this title, the petitioner shall be provided an opportunity to have such petition considered by the court in a de novo proceeding. If the petitioner demonstrates to the satisfaction of the court by a preponderance of the evidence that--

(i) in the case of a petition to initiate a proceeding for the issuance of a rule under section 2603 of this title or an order under section 2603 or 2604(e) of this title--

(I) information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the chemical substance to be subject to such rule or order; and

(II) in the absence of such information, the substance may present an unreasonable risk to health or the environment, or the substance is or will be produced in substantial quantities and it 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 it; or

(ii) in the case of a petition to initiate a proceeding for the issuance of a rule under section 2605(a) or 2607 of this title or an order under section 2604(f) of this title, the chemical substance or mixture to be subject to such rule or order presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation, under the conditions of use. [1]

the court shall order the Administrator to initiate the action requested by the petitioner. If the court finds that the extent of the risk to health or the environment alleged by the petitioner is less than the extent of risks to health or the environment with respect to which the Administrator is taking action under this chapter and there are insufficient resources available to the Administrator to take the action requested by the petitioner, the court may permit the Administrator to defer initiating the action requested by the petitioner until such time as the court prescribes.

(C) The court in issuing any final order in any action brought pursuant to subparagraph (A) may award costs of suit and reasonable fees for attorneys and expert witnesses if the court determines that such an award is appropriate. Any court, in issuing its decision in an action brought to review such an order, may award costs of suit and reasonable fees for attorneys if the court determines that such an award is appropriate.

(5) The remedies under this section shall be in addition to, and not in lieu of, other remedies provided by law.

CREDIT(S)

(Pub.L. 94-469, Title I, § 21, Oct. 11, 1976, 90 Stat. 2042; renumbered Title I, Pub.L. 99-519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub.L. 114-182, Title I, § 19(o), June 22, 2016, 130 Stat. 509.)

Notes of Decisions (12)

Footnotes

1 So in original. The period should probably be a semicolon.

15 U.S.C.A. § 2620, 15 USCA § 2620

Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

End of Document

United States Code Annotated Title 42. The Public Health and Welfare Chapter 85. Air Pollution Prevention and Control (Refs & Annos) Subchapter III. General Provisions

42 U.S.C.A. § 7607

§ 7607. Administrative proceedings and judicial review

Currentness

(a) Administrative subpenas; confidentiality; witnesses

In connection with any determination under section 7410(f) of this title, or for purposes of obtaining information under section 7521(b)(4) [1] or 7545(c)(3) of this title, any investigation, monitoring, reporting requirement, entry, compliance inspection, or administrative enforcement proceeding under the [2] chapter (including but not limited to section 7413, section 7414, section 7420, section 7429, section 7477, section 7524, section 7525, section 7542, section 7603, or section 7606 of this title),, [3] the Administrator may issue subpenas for the attendance and testimony of witnesses and the production of relevant papers, books, and documents, and he may administer oaths. Except for emission data, upon a showing satisfactory to the Administrator by such owner or operator that such papers, books, documents, or information or particular part thereof, if made public, would divulge trade secrets or secret processes of such owner or operator, the Administrator shall consider such record, report, or information or particular portion thereof confidential in accordance with the purposes of section 1905 of Title 18, except that such paper, book, document, or information may be disclosed to other officers, employees, or authorized representatives of the United States concerned with carrying out this chapter, to persons carrying out the National Academy of Sciences' study and investigation provided for in section 7521(c) of this title, or when relevant in any proceeding under this chapter. Witnesses summoned shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In case of contumacy or refusal to obey a subpena served upon any person under this subparagraph [4], the district court of the United States for any district in which such person is found or resides or transacts business, upon application by the United States and after notice to such person, shall have jurisdiction to issue an order requiring such person to appear and give testimony before the Administrator to appear and produce papers, books, and documents before the Administrator, or both, and any failure to obey such order of the court may be punished by such court as a contempt thereof.

(b) Judicial review

(1) A petition for review of action of the Administrator in promulgating any national primary or secondary ambient air quality standard, any emission standard or requirement under section 7412 of this title, any standard of performance or requirement under section 7411 of this title,, [3] any standard under section 7521 of this title (other than a standard required to be prescribed under section 7521(b)(1) of this title), any determination under section 7521(b)(5) [1] of this title, any control or prohibition under section 7545 of this title, any standard under section 7571 of this title, any rule issued under section 7413, 7419, or under section 7420 of this title, or any other nationally applicable regulations promulgated, or final action taken, by the Administrator under this chapter may be filed only in the United States Court of Appeals for the District of Columbia. A petition for review of the Administrator's action in approving or promulgating any implementation plan under section 7410 of this title or section 7411(d) of this title, any order under section 7411(j) of this title, under section 7412 of this title, under section 7419 of this title, or under section 7420 of this title, or his action under section 1857c-10(c)(2)(A), (B), or (C) of this title (as in effect before August 7, 1977) or under regulations thereunder, or revising regulations for enhanced monitoring and compliance certification programs under section 7414(a)(3) of this title, or any other final action of the Administrator under this chapter (including any

denial or disapproval by the Administrator under subchapter I) which is locally or regionally applicable may be filed only in the United States Court of Appeals for the appropriate circuit. Notwithstanding the preceding sentence a petition for review of any action referred to in such sentence may be filed only in the United States Court of Appeals for the District of Columbia if such action is based on a determination of nationwide scope or effect and if in taking such action the Administrator finds and publishes that such action is based on such a determination. Any petition for review under this subsection shall be filed within sixty days from the date notice of such promulgation, approval, or action appears in the Federal Register, except that if such petition is based solely on grounds arising after such sixtieth day, then any petition for review under this subsection shall be filed within sixty days after such grounds arise. The filing of a petition for reconsideration by the Administrator of any otherwise final rule or action shall not affect the finality of such rule or action for purposes of judicial review nor extend the time within which a petition for judicial review of such rule or action under this section may be filed, and shall not postpone the effectiveness of such rule or action.

(2) Action of the Administrator with respect to which review could have been obtained under paragraph (1) shall not be subject to judicial review in civil or criminal proceedings for enforcement. Where a final decision by the Administrator defers performance of any nondiscretionary statutory action to a later time, any person may challenge the deferral pursuant to paragraph (1).

(c) Additional evidence

In any judicial proceeding in which review is sought of a determination under this chapter required to be made on the record after notice and opportunity for hearing, if any party applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Administrator, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Administrator, in such manner and upon such terms and conditions as to [5] the court may deem proper. The Administrator may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original determination, with the return of such additional evidence.

(d) Rulemaking

(1) This subsection applies to--

(A) the promulgation or revision of any national ambient air quality standard under section 7409 of this title,

(B) the promulgation or revision of an implementation plan by the Administrator under section 7410(c) of this title,

(C) the promulgation or revision of any standard of performance under section 7411 of this title, or emission standard or limitation under section 7412(d) of this title, any standard under section 7412(f) of this title, or any regulation under section 7412(g)(1)(D) and (F) of this title, or any regulation under section 7412(m) or (n) of this title,

(D) the promulgation of any requirement for solid waste combustion under section 7429 of this title,

(E) the promulgation or revision of any regulation pertaining to any fuel or fuel additive under section 7545 of this title,

(F) the promulgation or revision of any aircraft emission standard under section 7571 of this title,

(G) the promulgation or revision of any regulation under subchapter IV-A (relating to control of acid deposition),

(H) promulgation or revision of regulations pertaining to primary nonferrous smelter orders under section 7419 of this title (but not including the granting or denying of any such order),

(I) promulgation or revision of regulations under subchapter VI of (relating to stratosphere and ozone protection),

(J) promulgation or revision of regulations under part C of subchapter I (relating to prevention of significant deterioration of air quality and protection of visibility),

(K) promulgation or revision of regulations under section 7521 of this title and test procedures for new motor vehicles or engines under section 7525 of this title, and the revision of a standard under section 7521(a)(3) of this title,

(L) promulgation or revision of regulations for noncompliance penalties under section 7420 of this title,

(M) promulgation or revision of any regulations promulgated under section 7541 of this title (relating to warranties and compliance by vehicles in actual use),

(N) action of the Administrator under section 7426 of this title (relating to interstate pollution abatement),

(O) the promulgation or revision of any regulation pertaining to consumer and commercial products under section 7511b(e) of this title,

(P) the promulgation or revision of any regulation pertaining to field citations under section 7413(d)(3) of this title,

(Q) the promulgation or revision of any regulation pertaining to urban buses or the clean-fuel vehicle, clean-fuel fleet, and clean fuel programs under part C of subchapter II,

(R) the promulgation or revision of any regulation pertaining to nonroad engines or nonroad vehicles under section 7547 of this title,

(S) the promulgation or revision of any regulation relating to motor vehicle compliance program fees under section 7552 of this title,

(T) the promulgation or revision of any regulation under subchapter IV-A (relating to acid deposition),

(U) the promulgation or revision of any regulation under section 7511b(f) of this title pertaining to marine vessels, and

(V) such other actions as the Administrator may determine.

The provisions of section 553 through 557 and section 706 of Title 5 shall not, except as expressly provided in this subsection, apply to actions to which this subsection applies. This subsection shall not apply in the case of any rule or circumstance referred to in subparagraphs (A) or (B) of subsection 553(b) of Title 5.

(2) Not later than the date of proposal of any action to which this subsection applies, the Administrator shall establish a rulemaking docket for such action (hereinafter in this subsection referred to as a "rule"). Whenever a rule applies only within a particular State, a second (identical) docket shall be simultaneously established in the appropriate regional office of the Environmental Protection Agency.

(3) In the case of any rule to which this subsection applies, notice of proposed rulemaking shall be published in the Federal Register, as provided under section 553(b) of Title 5, shall be accompanied by a statement of its basis and purpose and shall specify the period available for public comment (hereinafter referred to as the "comment period"). The notice of proposed rulemaking shall also state the docket number, the location or locations of the docket, and the times it will be open to public inspection. The statement of basis and purpose shall include a summary of--

(A) the factual data on which the proposed rule is based;

(B) the methodology used in obtaining the data and in analyzing the data; and

(C) the major legal interpretations and policy considerations underlying the proposed rule.

The statement shall also set forth or summarize and provide a reference to any pertinent findings, recommendations, and comments by the Scientific Review Committee established under section 7409(d) of this title and the National Academy of Sciences, and, if the proposal differs in any important respect from any of these recommendations, an explanation of the reasons for such differences. All data, information, and documents referred to in this paragraph on which the proposed rule relies shall be included in the docket on the date of publication of the proposed rule.

(4)(A) The rulemaking docket required under paragraph (2) shall be open for inspection by the public at reasonable times specified in the notice of proposed rulemaking. Any person may copy documents contained in the docket. The Administrator shall provide copying facilities which may be used at the expense of the person seeking copies, but the Administrator may waive or reduce such expenses in such instances as the public interest requires. Any person may request copies by mail if the person pays the expenses, including personnel costs to do the copying.

(B)(i) Promptly upon receipt by the agency, all written comments and documentary information on the proposed rule received from any person for inclusion in the docket during the comment period shall be placed in the docket. The transcript of public hearings, if any, on the proposed rule shall also be included in the docket promptly upon receipt from the person who transcribed such hearings. All documents which become available after the proposed rule has been published and which the Administrator determines are of central relevance to the rulemaking shall be placed in the docket as soon as possible after their availability.

(ii) The drafts of proposed rules submitted by the Administrator to the Office of Management and Budget for any interagency review process prior to proposal of any such rule, all documents accompanying such drafts, and all written comments thereon by other agencies and all written responses to such written comments by the Administrator shall be placed in the docket no later than the date of proposal of the rule. The drafts of the final rule submitted for such review process prior to promulgation and all such written comments thereon, all documents accompanying such drafts, and written responses thereto shall be placed in the docket no later than the date of promulgation.

(5) In promulgating a rule to which this subsection applies (i) the Administrator shall allow any person to submit written comments, data, or documentary information; (ii) 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; (iii) a transcript shall be kept of any oral presentation; and (iv) the Administrator shall keep the record of such proceeding open for thirty days after completion of the proceeding to provide an opportunity for submission of rebuttal and supplementary information.

(6)(A) The promulgated rule shall be accompanied by (i) a statement of basis and purpose like that referred to in paragraph (3) with respect to a proposed rule and (ii) an explanation of the reasons for any major changes in the promulgated rule from the proposed rule.

(B) The promulgated rule shall also be accompanied by a response to each of the significant comments, criticisms, and new data submitted in written or oral presentations during the comment period.

(C) The promulgated rule may not be based (in part or whole) on any information or data which has not been placed in the docket as of the date of such promulgation.

(7)(A) The record for judicial review shall consist exclusively of the material referred to in paragraph (3), clause (i) of paragraph (4)(B), and subparagraphs (A) and (B) of paragraph (6).

(B) Only an objection to a rule or procedure which was raised with reasonable specificity during the period for public comment (including any public hearing) may be raised during judicial review. If the person raising an objection can demonstrate to the Administrator that it was impracticable to raise such objection within such time or if the grounds for such objection arose after the period for public comment (but within the time specified for judicial review) and if such objection is of central relevance to the outcome of the rule, the Administrator shall convene a proceeding for reconsideration of the rule and provide the same procedural rights as would have been afforded had the information been available at the time the rule was proposed. If the Administrator refuses to convene such a proceeding, such person may seek review of such refusal in the United States court of appeals for the appropriate circuit (as provided in subsection (b)). Such reconsideration shall not postpone the effectiveness of the rule. The effectiveness of the rule may be stayed during such reconsideration, however, by the Administrator or the court for a period not to exceed three months.

(8) The sole forum for challenging procedural determinations made by the Administrator under this subsection shall be in the United States court of appeals for the appropriate circuit (as provided in subsection (b)) at the time of the substantive review of the rule. No interlocutory appeals shall be permitted with respect to such procedural determinations. In reviewing alleged procedural errors, the court may invalidate the rule only if the errors were so serious and related to matters of such central

relevance to the rule that there is a substantial likelihood that the rule would have been significantly changed if such errors had not been made.

(9) In the case of review of any action of the Administrator to which this subsection applies, the court may reverse any such action 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; or

(D) without observance of procedure required by law, if (i) such failure to observe such procedure is arbitrary or capricious, (ii) the requirement of paragraph (7)(B) has been met, and (iii) the condition of the last sentence of paragraph (8) is met.

(10) Each statutory deadline for promulgation of rules to which this subsection applies which requires promulgation less than six months after date of proposal may be extended to not more than six months after date of proposal by the Administrator upon a determination that such extension is necessary to afford the public, and the agency, adequate opportunity to carry out the purposes of this subsection.

(11) The requirements of this subsection shall take effect with respect to any rule the proposal of which occurs after ninety days after August 7, 1977.

(e) Other methods of judicial review not authorized

Nothing in this chapter shall be construed to authorize judicial review of regulations or orders of the Administrator under this chapter, except as provided in this section.

(f) Costs

In any judicial proceeding under this section, the court may award costs of litigation (including reasonable attorney and expert witness fees) whenever it determines that such award is appropriate.

(g) Stay, injunction, or similar relief in proceedings relating to noncompliance penalties

In any action respecting the promulgation of regulations under section 7420 of this title or the administration or enforcement of section 7420 of this title no court shall grant any stay, injunctive, or similar relief before final judgment by such court in such action.

(h) Public participation

It is the intent of Congress that, consistent with the policy of subchapter II of chapter 5 of Title 5, the Administrator in promulgating any regulation under this chapter, including a regulation subject to a deadline, shall ensure a reasonable period for public participation of at least 30 days, except as otherwise expressly provided in section [6] 7407(d), 7502(a), 7511(a) and (b), and 7512(a) and (b) of this title.

CREDIT(S)

(July 14, 1955, c. 360, Title III, § 307, as added Pub.L. 91-604, § 12(a), Dec. 31, 1970, 84 Stat. 1707; amended Pub.L. 92-157, Title III, § 302(a), Nov. 18, 1971, 85 Stat. 464; Pub.L. 93-319, § 6(c), June 22, 1974, 88 Stat. 259; Pub.L. 95-95, Title III, §§ 303(d), 305(a), (c), (f) to (h), Aug. 7, 1977, 91 Stat. 772, 776, 777; Pub.L. 95-190, § 14(a)(79), (80), Nov. 16, 1977, 91 Stat. 1404; Pub.L. 101-549, Title I, §§ 108(p), 110(5), Title III, § 302(g), (h), Title VII, §§ 702(c), 703, 706, 707(h), 710(b), Nov. 15, 1990, 104 Stat. 2469, 2470, 2574, 2681-2684.)

Notes of Decisions (357)

Footnotes

1 Repealed. See References in Text notes set out under this section.

2 So in original. Probably should be “this”.

3 So in original.

4 So in original. Probably should be “subsection,”.

5 So in original. The word “to” probably should not appear.

6 So in original. Probably should be “sections”.

42 U.S.C.A. § 7607, 42 USCA § 7607

Current through P.L. 116-91. Some statute sections may be more current, see credits for details.

End of Document

Code of Federal Regulations Title 40. Protection of Environment Chapter I. Environmental Protection Agency (Refs & Annos) Subchapter R. Toxic Substances Control Act Part 702. General Practices and Procedures (Refs & Annos) Subpart B. Procedures for Chemical Substance Risk Evaluations (Refs & Annos)

40 C.F.R. § 702.47

§ 702.47 Unreasonable risk determination.

Effective: September 18, 2017
Currentness

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.

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

Current through January 23, 2020; 85 FR 4188.

End of Document

Code of Federal Regulations Title 40. Protection of Environment Chapter I. Environmental Protection Agency (Refs & Annos) Subchapter R. Toxic Substances Control Act Part 751. Regulation of Certain Chemical Substances and Mixtures Under Section 6 of the Toxic Substances Control Act (Refs & Annos) Subpart B. Methylene Chloride

40 C.F.R. § 751.103

§ 751.103 Definitions.

Effective: May 28, 2019
Currentness

The definitions in subpart A of this part apply to this subpart unless otherwise specified in this section. In addition, the following definitions apply:

Consumer paint and coating removal means paint and coating removal performed by any natural person who uses a paint and coating removal product for any personal use without receiving remuneration or other form of payment.

Distribute in commerce has the same meaning as in section 3 of the Act, except that the term does not include retailers for purposes of §§ 751.107 and 751.109.

Paint and coating removal means application of a chemical or use of another method to remove, loosen, or deteriorate any paint, varnish, lacquer, graffiti, surface protectants, or other coating from a substrate, including objects, vehicles, architectural features, or structures.

Retailer means a person who distributes in commerce or makes available a chemical substance or mixture to consumer end users, including e-commerce internet sales or distribution. Any distributor with at least one consumer end user customer is considered a retailer. A person who distributes in commerce or makes available a chemical substance or mixture solely to commercial or industrial end users or solely to commercial or industrial businesses is not considered a retailer.

AUTHORITY: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

Current through January 23, 2020; 85 FR 4188.

End of Document

Code of Federal Regulations Title 40. Protection of Environment Chapter I. Environmental Protection Agency (Refs & Annos) Subchapter R. Toxic Substances Control Act Part 751. Regulation of Certain Chemical Substances and Mixtures Under Section 6 of the Toxic Substances Control Act (Refs & Annos) Subpart B. Methylene Chloride

40 C.F.R. § 751.105

§ 751.105 Consumer paint and coating removal.

Effective: May 28, 2019
Currentness

(a) After November 22, 2019, all persons are prohibited from manufacturing, processing and distributing in commerce methylene chloride for consumer paint and coating removal.

(b) After November 22, 2019, all persons are prohibited from distributing in commerce methylene chloride, including any methylene chloride containing products, for paint and coating removal to retailers.

(c) After November 22, 2019, all retailers are prohibited from distributing in commerce methylene chloride, including any methylene chloride containing products, for paint and coating removal.

AUTHORITY: 15 U.S.C. 2605, 15 U.S.C. 2625(l)(4).

Current through January 23, 2020; 85 FR 4188.

End of Document

TOXIC SUBSTANCES CONTROL ACT

P.L. 94-469, see page 90 Stat. 2003

Senate Report (Commerce Committee) No. 94-698, Mar. 16, 1976 [To accompany S. 3149]

House Report (Interstate and Foreign Commerce Committee) No. 94-1341, July 14, 1976 [To accompany H.R. 14032]

House Conference Report No. 94-1679, Sept. 23, 1976 [To accompany S. 3149]

Senate Conference Report No. 94-1302, Sept. 24, 1976 [To accompany S. 3149]

Cong. Record Vol. 122 (1976)

DATES OF CONSIDERATION AND PASSAGE

Senate March 26, September 28, 1976

House August 23, September 28, 1976

The Senate bill was passed in lieu of the House bill. The Senate Report and the House Conference Report are set out.

SENATE REPORT NO. 94-698

[page 1]

The Committee on Commerce having considered the bill (S. 3149) to regulate commerce and protect human health and the environment by requiring testing and necessary use restrictions on certain chemical substances, and for other purposes, reports favorably thereon and recommends that the bill do pass.

PURPOSE AND BRIEF DESCRIPTION

The purpose of S. 3149 is to prevent unreasonable risks of injury to health or the environment associated with the manufacture, processing, distribution in commerce, use, or disposal of chemical substances. The bill is designed to fill a number of regulatory gaps which currently exist. They are:

1. PREMARKET REVIEW

While certain environmental health statutes may be used to protect health and the environment from chemical substances, only pesticides, drugs, and food additives undergo premarket scrutiny prior to first manufacture. The Clean Air Act (77 Stat. 392), the Federal Water Pollution Control Act (66 Stat. 755), the Occupational Safety and Health Act (84 Stat. 1590), and the Consumer Product Safety Act (86 Stat. 1207), do not provide for this type of premarket scrutiny.

2. DIRECT REGULATION OF CHEMICALS

While air and water laws authorize limitations on discharges and emissions, the Occupational Safety and Health Act authorizes the

114TH CONGRESS
1st Session
HOUSE OF REPRESENTATIVES
REPORT
114–176

TSCA MODERNIZATION ACT OF 2015

JUNE 23, 2015.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. UPTON, from the Committee on Energy and Commerce, submitted the following

R E P O R T

[To accompany H.R. 2576]

[Including cost estimate of the Congressional Budget Office]

The Committee on Energy and Commerce, to whom was referred the bill (H.R. 2576) to modernize the Toxic Substances Control Act, and for other purposes, having considered the same, report favorably thereon with an amendment and recommend that the bill as amended do pass.

CONTENTS

The amendment is as follows:

Strike all after the enacting clause and insert the following:

publish a statement about the impacts of the chemical substance or mixture are largely retained in new section 6(c)(1)(A), with the consideration of substitutes moved to section 6(c)(1)(C) and the requirements for addressing chemical risks under other statutes administered by the Agency now in section 9(b). Under new TSCA subsection (c)(1)(B), the Administrator must impose requirements under the rule that, consistent with information published under subparagraph (A), are cost-effective, unless the Administrator determines that additional or different requirements described in subsection (a) are necessary to protect against the identified risk.

The Committee chose this process to ensure that the universe of data from which the Administrator would be making a cost-effectiveness decision would be limited to only that information provided and considered as part of the rulemaking record. The Committee does not expect EPA to analyze the cost-effectiveness of an open-ended group of possible requirements, but to focus on those that meet the subsection (a) purpose of controlling an unreasonable risk of injury. The Administrator need not test each control measure in a rulemaking for its cost-effectiveness. While the Committee's preference is that selected requirements be cost-effective, if no restriction is available that the Administrator determines cost-effective in managing the risk, the identified unreasonable risk must still be addressed.

New subsection (c)(1)(C) requires the Administrator, in deciding whether to prohibit or substantially restrict a specific use of a chemical substance or mixture and in setting an appropriate transition period for such action, to determine whether a technically and economically feasible alternative to a chemical that benefits health or the environment, compared to the use proposed to be prohibited or restricted, will be reasonably available as a substitute when the proposed prohibition or restriction takes effect.

New subsection (c)(1)(D) exempts replacement parts if they are designed prior to publication of the section 6(a) risk management rule in the Federal Register, unless the Administrator finds that they contribute significantly to the identified risk, including identified risks to identified potentially exposed subpopulations. Subsection (c)(1)(E) instructs the Administrator, when applying prohibitions or other restrictions to address an unreasonable risk of injury, to apply such prohibitions or restrictions to an article, on the basis of a chemical substance or mixture contained in that article, only to the extent necessary to protect against the unreasonable risk of injury from that article.

Section 4(c) repeals the requirement for informal hearings, including cross examination of witnesses, found in TSCA section 6(c)(3) and repeals the availability of compensation of attorney's fees, expert witness fees, and other costs of participating in a proceeding for the promulgation of a subsection (a) rule found in TSCA paragraph 6(c)(4).

Further, Section 4(d) adds a requirement at the end of section 6(d)(2)(B) providing for a reasonable transition period for any rule promulgated under section 6(a).

Section 4(e) of the TSCA Modernization Act adds three new subsections to the end of TSCA section 6 to address three distinct areas.

DETAILED ANALYSIS AND ADDITIONAL VIEWS OF DEMOCRATIC MEMBERS ON THE MOTION TO CONCUR IN THE HOUSE AMENDMENT TO THE SENATE AMENDMENT TO THE BILL H.R. 2576 ENTITLED ''AN ACT TO MODERNIZE THE TOXIC SUBSTANCES CONTROL ACT, AND FOR OTHER PURPOSES'' JUNE 7, 2016

As the lead Senate Democratic negotiators on H.R. 2576, (hereinafter referred to as the Frank R. Lautenberg Chemical Safety for the 21st Century Act), we submit the following additional views that describe the intent of the negotiators on elements of the final bill text.

1. ''WILL PRESENT''

Existing TSCA as in effect before the date of enactment of Frank R Lautenberg Chemical Safety for the 21st Century Act includes the authority, contained in several sections (see, for example, section 6(a)), for EPA to take regulatory actions related to chemical substances or mixtures if it determines that the chemical substance or mixture ''presents or will present'' an unreasonable risk to health or the environment.

The Frank R. Lautenberg Chemical Safety for the 21st Century Act includes language that removes all instances of ''will present'' from existing TSCA and the amendments thereto. This does not reflect an intent on the part of Congressional negotiators to remove EPA's authority to consider future or reasonably anticipated risks in evaluating whether a chemical substance or mixture presents an unreasonable risk to health or the environment. In fact, a new definition added to TSCA explicitly provides such authority and a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur:

''(4) The term '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'';

2. MIXTURES

In section 6(b) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, EPA is directed to undertake risk evaluations on chemical substances in order to determine whether they pose an unreasonable risk to health or the environment. Some have questioned whether the failure to explicitly authorize risk evaluations on mixtures calls into question EPA's authority to evaluate the risks from chemical substances in mixtures.

The definition of 'conditions of use' described above plainly covers all uses of a chemical substance, including its incorporation in a mixture, and thus would clearly enable and require, where relevant, EPA to evaluate the risks of the chemical substance as a component of a mixture.

3. NEW CHEMICALS

While existing TSCA does not preclude EPA from reviewing new chemicals and significant new uses following notification by the manufacturer or processor, it does not require EPA to do so or to reach conclusions on the potential risks of all such chemicals before they enter the marketplace. EPA has authority to issue orders blocking or limiting production or other activities if it finds that available information is inadequate and the chemical may present an unreasonable risk, but the burden is on EPA to invoke this authority; if it fails to do so within the 90–180 day review period, manufacture of the new chemical can automatically commence. This bill makes significant changes to this passive approach under current law: For the first time, EPA will be required to review all new chemicals and significant new uses and make an affirmative finding regarding the chemical's or significant new use's potential risks as a condition for commencement of manufacture for commercial purposes and, in the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk, manufacture will not be allowed to occur. If EPA finds that it lacks sufficient information to evaluate the chemical's or significant new use's risks or that the chemical or significant new use does or may present an unreasonable risk, it is obligated to issue an order or rule that precludes market entry or imposes conditions sufficient to prevent an unreasonable risk. EPA can also require additional testing. Only chemicals and significant new uses that EPA finds are not likely to present an unreasonable risk can enter production without restriction. This affirmative approach to better ensuring the safety of new chemicals entering the market is essential to restoring the public's confidence in our chemical safety system.

4. UNREASONABLE RISK

TSCA as in effect before the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act authorized EPA to regulate chemical substances if it determined that the chemical substance ''presents or will present an unreasonable risk of injury to health or the environment.'' In its decision in Corrosion Proof Fittings vs EPA, the U.S. Court of Appeals, 5th Circuit overturned EPA's proposed ban on asbestos, in part because it believed that

''In evaluating what is ''unreasonable,'' the EPA is required to consider the costs of any proposed actions and to ''carry out this chapter in a reasonable and prudent manner [after considering] the environmental, economic, and social impact of any action.'' 15 U.S.C. §2601(c).

As the District of Columbia Circuit stated when evaluating similar language governing the Federal Hazardous Substances Act, ''[t]he requirement that the risk be 'unreasonable' necessarily involves a balancing test like that familiar in tort law: The regulation may issue if the severity of the injury that may result from the product, factored by the likelihood of the injury, offsets the harm the regulation itself imposes upon manufacturers and consumers.'' Forester v. CPSC, 559 F.2d 774 789 (D.C.Cir.1977). We have quoted this language approvingly when evaluating other statutes using similar language. See, e.g., Aqua Slide, 569 F.2d at 839.''

The Frank R Lautenberg Chemical Safety for the 21st Century Act clearly rejects that approach to determining what ''unreasonable risk of injury to health or the environment'' means, by adding text that directs EPA to determine whether such risks exist ''without consideration of costs or other nonrisk factors'' and, if they do, to promulgate a rule that ensures ''that the chemical substance no longer presents such risk.'' In this manner, Congress has ensured that when EPA evaluates a chemical to determine whether it poses an unreasonable risk to health or the environment and regulates the chemical if it does, the Agency may not apply the sort of ''balancing test'' described above.

5. PRIORITIZATION

Section 6(b) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, defines high-priority chemical substances and low-priority chemical substances as follows:

''(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 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.

''(ii) LOW–PRIORITY SUBSTANCES.—The Administrator shall designate a chemical substance as a low-priority substance if the Administrator concludes, based on information sufficient to establish, without consideration of costs or other nonrisk factors, that such substance does not meet the standard identified in clause (i) for designating a chemical substance a high-priority substance.''

The direction to EPA for the designation of low-priority substances is of note in that it requires such designations to be made only when there is ''information sufficient to establish'' that the standard for designating a substance as a high-priority substance is not met. Clear authority is provided under section 4(a)(2)(B), as created in the Frank R Lautenberg Chemical Safety for the 21st Century Act, to enable EPA to obtain the information needed to prioritize chemicals for which information is initially insufficient. The bill text also goes on to state that if ''the information available to the Administrator at the end of such an extension [for testing of a chemical substance in order to determine its priority designation] remains insufficient to enable the designation of the chemical substance as a low-priority substance, the Administrator shall designate the chemical substance as a high-priority substance.''

These provisions are intended to ensure that the only chemicals to be designated low-priority are those for which EPA both has sufficient information and, based on that information, affirmatively concludes that the substance does not warrant a finding that it may present an unreasonable risk.

6. INDUSTRY REQUESTED CHEMICALS

Sec. 6(b)(4)(E) sets the percentage of risk evaluations that the Administrator shall conduct at industry's request at between 25 percent (if enough requests are submitted) and 50 percent. The Administrator should set up a system to ensure that those percentages are met and not exceeded in each fiscal year. An informal effort that simply takes requests as they come in and hopes that the percentages will work out does not meet the requirement that the Administrator ''ensure'' that the percentages be met. Also, clause (E)(ii) makes clear that industry requests for risk evaluations ''shall be'' subject to fees. Therefore, if at any point the fees imposed by the Frank Lautenberg Act (which are subject to a termination in section 26(b)(6)) are allowed to lapse, industry's opportunity to seek risk evaluations will also lapse and the minimum 25 percent requirement will not apply.

7. PACE OF AND LONG-TERM GOAL FOR EPA SAFETY REVIEWS OF EXISTING CHEMICALS

Existing TSCA grandfathered in tens of thousands of chemicals to the inventory without requiring any review of their safety. The Frank R. Lautenberg Chemical Safety for the 21st Century Act sets in motion a process under which EPA will for the first time systematically review the safety of chemicals in active commerce. While this will take many years, the goal of the legislation is to ensure that all chemicals on the market get such a review. The initial targets for numbers of reviews are relatively low, reflecting current EPA capacity and resources. These targets represent floors, not ceilings, and Senate Democratic negotiators expect that as EPA begins to collect fees, gets procedures established and gains experience, these targets can be exceeded in furtherance of the legislation's goals.

8. "MAXIMUM" EXTENT PRACTICABLE

Several sections of the Frank R. Lautenberg Chemical Safety for the 21st Century Act include direction to EPA to take certain actions to "the extent practicable", in contrast to language in S 697 as reported by the Senate that actions be taken to "the maximum extent practicable." During House-Senate negotiations on the bill, Senate negotiators were informed that House Legislative Counsel believed the terms "extent practicable" and "maximum extent practicable" are synonymous, and ultimately Congress agreed to include "extent practicable" in the Frank R. Lautenberg Chemical Safety for the 21st Century Act with the expectation that no change in meaning from S 697 as reported by the Senate be inferred from that agreement.

9. COST CONSIDERATIONS IN RULEMAKING

Section 6(c)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act lists what is required in analysis intended to support an EPA rule for a chemical substance or mixture:

"(2) REQUIREMENTS FOR RULE.—"(A) STATEMENT OF EFFECTS.—In proposing and promulgating a rule under subsection (a) with respect to a chemical substance or mixture, the Administrator shall consider and publish a statement based on reasonably available information with respect to—

"(i) the effects of the chemical substance or mixture on health and the magnitude of the exposure of human beings to the chemical substance or mixture;

"(ii) the effects of the chemical substance or mixture on the environment and the magnitude of the exposure of the environment to such substance or mixture;

"(iii) the benefits of the chemical substance or mixture for various uses; and

"(iv) the reasonably ascertainable economic consequences of the rule, including consideration of—

"(I) the likely effect of the rule on the national economy, small business, technological innovation, the environment, and public health;

"(II) the costs and benefits of the proposed and final regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator; and

"(III) the cost effectiveness of the proposed regulatory action and of the 1 or more primary alternative regulatory actions considered by the Administrator.

The language above specifies the information on effects, exposures and costs that EPA is to consider in determining how to regulate a chemical substance that presents an unreasonable risk as determined in EPA's risk evaluation.

Senate Democratic negotiators clarify that sections 6(c)(2)(A)(i) and (ii) do not require EPA to conduct a second risk evaluation-like analysis to identify the specified information, but rather, can satisfy these requirements on the basis of the conclusions regarding the chemical's health and environmental effects and exposures in the risk evaluation itself.

The scope of the statement EPA is required to prepare under clauses (i)–(iv) is bounded in two important respects. First, it is to be based on information reasonably available to EPA, and hence does not require new information collection or development. Second, EPA's consideration of costs and benefits and cost-effectiveness is limited to the requirements of the rule itself and the 1 or more "primary" alternatives it considered, not every possible alternative. The role of the statement required under subparagraph (c)(2)(A) in selecting the restrictions to include in its rule is delineated in subparagraph (c)(2)(B). Under this provision, EPA must "factor in" the considerations described in the statement "to the extent practicable" and "in accordance with subsection (a)." As revised, subsection (a) deletes the paralyzing "least burdensome" requirement in the existing law and instructs that EPA's rule must ensure that the chemical substance or mixture "no longer presents" the unreasonable risk identified in the risk evaluation. Thus, it is clear that the considerations in the statement required under subparagraph (c)(2)(A) do not require EPA to demonstrate benefits outweigh costs, to definitively determine or select the least-cost alternative, or to select an option that is demonstrably cost-effective or is the least burdensome adequately protective option. Rather, it requires only that EPA take into account the specified considerations in deciding among restrictions to impose, which must be sufficient to ensure that the subject chemical substance no longer presents the unreasonable risk EPA has identified. The Frank R. Lautenberg Chemical Safety for the 21st Century Act clearly rejects the regulatory approach and framework that led to the failed asbestos ban and phase-out rule of 1989 in Corrosion Proof Fittings v. EPA 947 F.2d 1201 (5th Cir. 1991).

10. "MINIMUM" LABELING REQUIREMENTS

Section 6(a) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, ensures that the requirements EPA can impose to address an unreasonable risk to health or the environment include requiring "clear and adequate minimum" warnings. The addition of the word "minimum" was intended to avoid the sort of litigation that was undertaken in Wyeth v. Levine, 555 U.S. 555 (2009), when a plaintiff won a Supreme Court decision after alleging that the harm she suffered from a drug that had been labeled in accordance with FDA requirements had nevertheless been inadequately labeled under Vermont law. This ensures that manufacturers or processors of chemical substances and mixtures can always take additional measures, if in the interest of protecting health and the environment, it would be reasonable to do so.

11. CRITICAL USE EXEMPTIONS

Section 6(g) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, authorizes EPA to exempt specific conditions of use from otherwise applicable section 6(a) rule requirements, if EPA makes specified findings. Section 6(g)(4) in turn requires EPA to include in such an exemption conditions that are "necessary to protect health and the environment while achieving the purposes of the exemption." It is Congress' intent that the conditions EPA imposes will protect health and the environment to the extent feasible, recognizing that, by its nature, an exemption will allow for activities that present some degree of unreasonable risk.

12. REGULATORY COMPLIANCE

Several sections of the Frank R. Lautenberg Chemical Safety for the 21st Century Act clarify the Congressional intent that compliance with federal EPA standards, rules or other requirements shall not preclude liability in circumstances where a reasonable manufacturer or processor or distributor of a chemical substance or mixture could or should have taken additional measures or precautions in the interest of protecting public health and the environment.

13. TSCA AS THE PRIMARY STATUTE FOR THE REGULATION OF TOXIC SUBSTANCES

EPA's authorities and duties under section 6 of TSCA have been significantly expanded under the Frank R. Lautenberg Chemical Safety for the 21st Century Act, now including comprehensive deadlines and throughput expectations for chemical prioritization, risk evaluation, and risk management. The interagency referral process and the intra-agency consideration process established under Section 9 of existing TSCA must now be regarded in a different light since TSCA can no longer be construed as a "gap-filler" statutory authority of last resort. The changes in section 9 are consistent with this recognition and do not conflict with the fundamental expectation that, where EPA concludes that a chemical presents an unreasonable risk, the Agency should act in a timely manner to ensure that the chemical substance no longer presents such risk. Thus, once EPA has reached this conclusion, Section 9(a) is not intended to supersede or modify the Agency's obligations under Sections 6(a) or 7 to address risks from activities involving the chemical substance, except as expressly identified in a section 9(a) referral for regulation by another agency which EPA believes has sufficient authority to eliminate the risk and where the agency acts in a timely and effective manner to do so.

Regarding EPA's consideration of whether to use non-TSCA EPA authorities in order to address unreasonable chemical risks identified under TSCA, the new section 9(b)(2) merely consolidates existing language which was previously split between section 6(c) and section 9(b). It only applies where the Administrator has already determined that a risk to health or the environment associated with a chemical substance or mixture could be eliminated or reduced to a sufficient extent by additional actions taken under other EPA authorities. It allows the Administrator substantial discretion to use TSCA nonetheless, and it certainly does not reflect that TSCA is an authority of last resort in such cases. Importantly, the provision adds a new qualification, not in original TSCA, that the required considerations are to be "based on information reasonably available to the Administrator" to ensure that such considerations do not require additional information to be collected or developed. Furthermore, none of these revisions were intended to alter the clear intent of Congress, reflected in the original legislative history of TSCA, that these decisions would be completely discretionary with the Administrator and not subject to judicial review in any manner.

14. DISCLOSURE OF CONFIDENTIAL BUSINESS INFORMATION

S. 697 as passed by the Senate included several requirements as amendments to sections 8 and 14 of existing TSCA that direct EPA to "promptly" make confidential business information public when it determines that protections against disclosure of such information should no longer apply. The Frank R. Lautenberg Chemical Safety for the 21st Century Act instead directs EPA to remove the protections against disclosure when it determines that they should no longer apply. Because EPA informed Senate negotiators that its practice is to promptly make public information that is no longer protected against disclosure, we see no difference or distinction in meaning between the language in S. 697 as passed and the Frank R. Lautenberg Chemical Safety for the 21st Century Act, and expect EPA to continue its current practice of affirmatively making public information that is not or no longer protected from disclosure as expeditiously as possible.

Subsection 14(d)(9) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, further clarifies the Congressional intent that any information required pursuant to discovery, subpoena, court order, or any other judicial process is always allowable and discoverable under State and Federal law, and not protected from disclosure.

15. CHEMICAL IDENTITY

Section 14(b)(2) of the bill retains TSCA's provision making clear that information from health and safety studies is not protected from disclosure. It also retains TSCA's two existing exceptions from disclosure of information from health and safety studies: for information where disclosure would disclose either how a chemical is manufactured or processed or the portion a chemical comprises in a mixture. A clarification has been added to the provision to note explicitly that the specific identity of a chemical is among the types of information that need not be disclosed, when disclosing health and safety information, if doing so would also disclose how a chemical is made or the portion a chemical comprises in a mixture. This clarification does not signal any Congressional intent to alter the meaning of the provision, only to clarify its intent.

16. ''REQUIREMENTS'''

Subsection 5(i)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance.

Subsection 6(j) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance.

17. STATE-FEDERAL RELATIONSHIP

Sections 18(a)(1)(B) and 18(b)(1) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, refer to circumstances under which a state may not establish or continue to enforce a ''statute, criminal penalty, or administrative action'' on a chemical substance. Section 18(b)(2) states that ''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''. In an email transmitted by Senate Republican negotiators at 11:45 AM on May 23, 2016, the Senate requested that House Legislative Counsel delete the word ''assessed,'' but this change was not made in advance of the 12 PM deadline to file the bill text with the House Rules Committee. The Senate's clear intent was not to change or in any way limit the meaning of the phrase ''criminal penalty'' in section 18(b)(2).

Section 18(d)(I) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, references ''risk evaluations''' on chemical substances that may be conducted by states or political subdivisions of states with the clear intent to describe the circumstances in which such efforts would not be preempted by federal action. The term ''Risk Evaluation'' may not be universally utilized in every state or political subdivision of a state, but researching each analogous term used in each state or political subdivision of a state in order to explicitly list it was neither realistic nor possible. The use of this term is not intended to be in any way limiting.

Section 18(d)(1)(A)(ii) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, fully preserves the authority of states or political subdivisions of states to impose ''information obligation'' requirements on manufacturers or processors with respect to chemicals they produce or use. The provision cites examples of such obligations: reporting and monitoring or ''other information obligations.'' These may include, but are not limited to, state requirements related to information, such as companies' obligations to disclose use information, to provide warnings or to label products or chemicals with certain information regarding risks and recommended actions to reduce exposure or environmental release.

Section 18(d)(2) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, specifies that nothing in this section shall modify the preemptive effect of any prior rule or order by the Administrator prior to the effective date, responding to concerns that prior EPA action on substances such as polychlorinated biphenyls would be potentially immunized from liability for injury or harm.

Section 18(e) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, grandfathers existing and enacted state laws and regulatory actions, and requirements imposed now or in the future under the authority of state laws that were in effect on August 31, 2003.

Section 18(f) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, provides discretionary and mandatory waivers which exempt regulatory action by states and their political subdivisions from any federal preemptive effect. In particular, Subsection 18(f)(2)(B) specifies that, where requested, EPA shall grant a waiver from preemption under subsection (b) upon the enactment of any statute, or the proposal or completion of a preliminary administrative action, with the intent of prohibiting or otherwise restricting a chemical substance or mixture, provided these actions occur during the 18-month period after EPA initiates the prioritization process and before EPA publishes the scope of the risk evaluation for the chemical substance (which cannot be less than 12 months after EPA initiates the prioritization process).

Section 18(g) of TSCA, as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, specifies that no preemption of any common law or statutory causes of action for civil relief or criminal conduct shall occur, and that nothing in this Act shall be interpreted as dispositive or otherwise limiting any civil action or other claim for relief. This section also clarifies the Congressional intent to ensure that state requirements, including legal causes of action arising under statutory or common law, are not preempted or limited in any way by EPA action or inaction on a chemical substance. This section further clarifies Congress' intent that no express, implied, or actual conflict exists between any federal regulatory action and any state, federal, or maritime tort action, responding to the perceived conflict contemplated in Geier v. American Honda Motor Co., 529 U.S. 861 (2000) and its progeny.

18. FEES

Fees under section 26(b), as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, are authorized to be collected so that 25% of EPA's overall costs to carry out section 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information, are defrayed, subject to a $25,000,000 cap (that itself can be adjusted for inflation or if it no longer provides 25% of EPA's costs listed above). While the collection of fees is tied to the submission of particular information under sections 4 and 5 or the manufacturing or processing of a particular chemical substance undergoing a risk evaluation under section 6, in general the use of these fees is not limited to defraying the cost of the action that was the basis for payment of the fee. The exception to this general principle is for fees to defray the cost of conducting manufacturer requested risk evaluations, which are independent of the $25 million cap or 25% limit. These must be spent on the particular risk evaluation that was the basis for payment of the fee. This limitation applies only to the fee collected for the purpose of conducting the risk evaluation and does not prevent EPA from collecting further fees from such persons for other purposes for which payment of fees are authorized under the section. For example, if a manufacturer-requested risk evaluation later leads to risk management action, EPA may assign further fees to manufacturers and processors of that substance, subject to the $25,000,000 cap and the requirement to not exceed 25% of overall program costs for carrying out sections 4, 5, and 6, and to collect, process, review, provide access to and protect from disclosure information.

We also note that some have raised the possibility that section 26(b)(4)(B)(i)(I), as amended by the Frank R Lautenberg Chemical Safety for the 21st Century Act, could be read to exclude the cost of risk evaluations, other than industry-requested risk evaluations, from the costs that can be covered by fees. This was not the intent and is not consistent with the statutory language. As clearly indicated in section 26(b)(1), the amended law provides that manufacturers and processors of chemicals subject to risk evaluations be subject to fees, and that fees be collected to defray the cost of administering sections 4, 5, and 6, and of collecting, processing, reviewing and providing access to and protecting from disclosure information. Risk evaluations are a central element of section 6. And as demonstrated by section 6(b)(4)(F)(i), the intent of the bill is that the EPA-initiated risk evaluations be defrayed at the 25% level (subject to the $25,000,000 cap), in contrast to the industry-initiated evaluations, which are funded at the 50% or 100% level. The final citation in section 26(b)(4)(B)(i) should be read as section 6(b)(4)(C)(ii), as it is in section 6(b)(4)(F)(i), not to section 6(b) generally.

19. SCIENTIFIC STANDARDS

The term ''weight of evidence'' refers to a systematic review method that uses a pre-established protocol to comprehensively, objectively, transparently, and consistently, identify and evaluate each stream of evidence, including strengths, limitations, and relevance of each study and to integrate evidence as necessary and appropriate based upon strengths, limitations, and relevance.

This requirement is not intended to prevent the Agency from considering academic studies, or any other category of study. We expect that when EPA makes a weight of the evidence decision it will fully describe its use and methods.

20. PARTIAL RISK EVALUATIONS

Section 26(1)(4) of TSCA, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, states

''(4) CHEMICAL SUBSTANCES WITH COMPLETED RISK ASSESSMENTS.—With respect to a chemical substance listed in the 2014 update to the TSCA Work Plan for Chemical Assessments for which the Administrator has published a completed risk assessment prior to the date of enactment of the Frank R. Lautenberg Chemical Safety for the 21st Century Act, the Administrator may publish proposed and final rules under section 6(a) that are consistent with the scope of the completed risk assessment for the chemical substance and consistent with other applicable requirements of section 6.''

EPA has completed risk assessments on TCE, NMP, and MC, but has not yet proposed

or finalized section 6(a) rules to address the risks that were identified. The risk assessments for these chemicals were not conducted across all conditions of use. During the bi-cameral negotiations, EPA expressed the view that, rather than reexamine and perhaps broaden the scope of these assessments, it is better to proceed with proposed and final rules on the covered chemicals to avoid any delay in the imposition of important public health protections that are known to be needed. Congress shared these concerns. The language House-Senate negotiators included above is intended to allow EPA to proceed with the regulation of these substances if the scope of the proposed and final rules is consistent with the scope of the risk assessments conducted on these substances.

21. SNURS FOR ARTICLES

Section 5(a)(5) addresses the application of significant new use rules (SNURs) to articles or categories of articles containing substances of concern. It provides that in promulgating such SNURs, EPA must make ''an affirmative finding . . . . that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.'' This language clarifies that potential exposure is a relevant factor in applying SNURs to articles. Exposure is a relevant factor in identifying other significant new uses of a chemical substance as well. It is not intended to require EPA to conduct an exposure assessment or provide evidence that exposure to the substance through the article or category of articles will in fact occur. Rather, since the goal of SNURs is to bring to EPA's attention and enable it to evaluate uses of chemicals that could present unreasonable risks, a reasonable expectation of possible exposure based on the nature of the substance or the potential uses of the article or category of articles will be sufficient to ''warrant notification.'' EPA has successfully used the SNUR authority in the existing law to provide for scrutiny of imported articles (many of which are widely used consumer products) that contain unsafe chemicals that have been restricted or discontinued in the U.S. and it's critical that SNURs continue to perform this important public health function under the amended law.

22. COMPLIANCE DEADLINES

The amended law expands on existing section 6(d) by providing that rules under section 6 must include ''mandatory compliance dates.'' These dates can vary somewhat with the type of restriction being imposed but, in general, call for compliance deadlines that ''shall be as soon as practicable, but not later than 5 years after the promulgation of the rule.'' While EPA could in unusual circumstances delay compliance for as long as five years, this should be the exception and not the norm. To realize the risk reduction benefits of the rule, it is expected that compliance deadlines will be as soon as practicable after the rule's effective date as directed in new paragraph 6(d)(1).

Senator Barbara Boxer, Ranking Member, Environment and Public Works Committee.

Senator Edward J. Markey, Ranking Member, Subcommittee on Superfund, Waste Management and Regulatory Oversight, Environment and Public Works Committee, and cosponsor, Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Senator Tom Udall, lead Democratic author and sponsor, Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Senator Jeffrey A. Merkley, cosponsor, Frank R. Lautenberg Chemical Safety for the 21st Century Act.

Mr. MERKLEY. I yield the floor.

Mrs. GILLIBRAND. Mr. President, I know that everyone here shares a desire to fix our chemical safety law, the Toxic Substances Control Act, and I appreciate the years of hard work that my colleagues, starting with the late Senator from New Jersey, Frank Lautenberg, put in to try to make this bill the best bipartisan compromise it could be.

So many parts of this bill strengthen the standards and review process for chemicals, and I am pleased that we will finally be able to effectively regulate chemicals on a Federal level.

However, there is one part of the bill that still concerns me: the preemption of State laws.

Right now, a number of States, including New York, have taken the lead in chemical safety and have set standards for their own citizens that are higher than the standards set by the EPA.

These State actions have brought the chemical companies to the table to finally create a strong federal system for reviewing chemicals for safety.

But this bill would significantly limit the rights of individual States to set their own chemical safety standards from this day forward.

It would prevent a State from regulating or enforcing regulations on a chemical if the EPA is studying but has not yet ruled on the safety of that chemical.

But the EPA's review process can take far longer than a State's review process.

As a result, if a Governor or a State legislature wanted to develop their own rules to protect their citizens from a particular chemical that they knew was toxic and posing an imminent threat, their hands would be tied because of this law, and it would be left to the EPA to determine whether the State's science is valid.

Why would we take away this right from our States?

The only recourse for States is a burdensome waiver process that does not guarantee that a State will prevail in obtaining a waiver to continue to protect the health of its families. That is not enough.

When it comes to protecting public health, I firmly believe that Federal laws should set a floor, not a ceiling, and States should continue to have the right to protect their citizens from toxic chemicals—especially while they wait for the EPA to complete their own lengthy studies.

No State should be prevented from acting to protect the health and safety of its people when the Federal Government fails to act.

No State should be prevented from banning a dangerous chemical, simply because the EPA is taking time to review the substance.

So despite all the hard work of my colleagues and the progress that has been made, I cannot vote to undermine my State's ability to protect our constituents, and I will vote no on this bill.

Thank you.

CONGRESSIONAL INTENT BEHIND SPECIFIC PROVISIONS OF THE BILL

Mr. INHOFE. Senator VITTER and I rise today to discuss a few provisions in the bill with the desire of clarifying what the Congressional intent was behind specific provisions of the legislation. Senator VITTER, I would like to start with a question to you on the purpose of the term ''conditions of use'' and how that term is supposed to be applied by EPA in risk evaluations?

Mr. VITTER. Thank you Senator INHOFE. There are many important provisions of this law and I think clarifying what Congress intended is very important to ensure the legislative intent is understood and followed. To specifically address your first question, the term ''conditions of use'' is specifically defined as 'the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.' The conditions of use of a chemical substance drive the potential for exposure to a chemical. Exposure potential, when integrated with the hazard potential of a chemical, determines a chemical's potential for risk. So EPA's understanding of a chemical's conditions of use—and importantly it is the circumstances 'the Administrator' determines—will be critical to EPA's final determination of whether a chemical is safe or presents an unreasonable risk that must be controlled. Finally, to address your question of how this is supposed to be applied by EPA in risk evaluations, it is important to note that many TSCA chemicals have multiple uses—industrial, commercial and consumer uses. EPA has identified subcategories of chemical uses for regular chemical reporting requirements, so the Agency is well aware that some categories of uses pose greater potential for exposure than others and that the risks from many categories of uses are deemed negligible or already well controlled. The language of the compromise makes clear that EPA has to make a determination on all conditions of use considered in the scope but the 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. Without this discretion to focus chemical risk assessments on certain conditions of use, the Agency's job would be more difficult.

Mr. INHOFE. Thank you, Senator VITTER. That response raised an interesting follow up question I would like

Public Law 114–182
114th Congress

An Act

June 22, 2016
[H.R. 2576]

To modernize the Toxic Substances Control Act, and for other purposes.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

Frank R. Lautenberg Chemical Safety for the 21st Century Act. 15 USC 2601 note.

SECTION 1. SHORT TITLE; TABLE OF CONTENTS.

(a) SHORT TITLE.—This Act may be cited as the "Frank R. Lautenberg Chemical Safety for the 21st Century Act".

(b) TABLE OF CONTENTS.—The table of contents of this Act is as follows:

TITLE I—CHEMICAL SAFETY

SEC. 2. FINDINGS, POLICY, AND INTENT.

Section 2(c) of the Toxic Substances Control Act (15 U.S.C. 2601(c)) is amended by striking "proposes to take" and inserting "proposes as provided".

SEC. 3. DEFINITIONS.

Section 3 of the Toxic Substances Control Act (15 U.S.C. 2602) is amended—

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.";

(8) in subsection (h)—

(A) in paragraph (1)(A), by inserting ", 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";

(B) in paragraph (2), by striking "data" each place it appears and inserting "information"; and

(C) in paragraph (4), by striking ". A rule promulgated" and all that follows through "section 6(c)" and inserting ", including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use"; and

(9) by amending subsection (i) to read as follows:

"(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 Act, 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).".

SEC. 6. PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES.

Section 6 of the Toxic Substances Control Act (15 U.S.C. 2605) is amended—

(1) by striking the section heading and inserting "**PRIORITIZATION, RISK EVALUATION, AND REGULATION OF CHEMICAL SUBSTANCES AND MIXTURES**";

(2) in subsection (a)—

(A) by striking "finds that there is a reasonable basis to conclude" and inserting "determines in accordance with subsection (b)(4)(A)";

(B) by striking "or will present";

(C) by inserting "and subject to section 18, and in accordance with subsection (c)(2)," after "shall by rule";

(D) by striking "to protect adequately against such risk using the least burdensome requirements" and inserting "so that the chemical substance or mixture no longer presents such risk";

(E) by inserting "or otherwise restricting" after "prohibiting" in paragraphs (1)(A) and (2)(A);

(F) by inserting "minimum" before "warnings" both places it appears in paragraph (3);

(G) by striking "and monitor or conduct tests" and inserting "or monitor or conduct tests" in paragraph (4); and

(H) in paragraph (7)—

(i) by striking "such unreasonable risk of injury" and inserting "such determination"; and