

1 UNITED STATES COURT OF APPEALS
2 FOR THE SECOND CIRCUIT

3
4 August Term, 2020

5
6 (Argued: March 4, 2021 Decided: September 1, 2021)

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8 Docket Nos. 19-1042(L); 19-1044; 19-2329
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13 LABOR COUNCIL FOR LATIN AMERICAN ADVANCEMENT; NATURAL
14 RESOURCES DEFENSE COUNCIL, INC.; VERMONT PUBLIC INTEREST
15 RESEARCH GROUP; SAFER CHEMICALS HEALTHY FAMILIES; LAUREN
16 ATKINS; WENDY HARTLEY; and HALOGENATED SOLVENTS
17 INDUSTRY ALLIANCE, INC.,

18
19 *Petitioners,*

20
21 v.

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23 UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; and
24 MICHAEL S. REGAN,* as Administrator of the United States Environmental
25 Protection Agency,
26

27 *Respondents.*
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29 _____

30 Before:

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32 LEVAL, CABRANES, and RAGGI, *Circuit Judges.*
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* Pursuant to Federal Rule of Appellate Procedure 43(c)(2), Administrator Michael S. Regan is automatically substituted as Respondent. The Clerk of the Court is respectfully directed to amend the caption as set forth above.

1 Petitioner Halogenated Solvents Industry Alliance, Inc. (“HSIA”)
2 challenges a Final Rule published by the Environmental Protection Agency
3 (“EPA”) restricting access by consumers to methylene chloride, a dangerous
4 chemical used in paint removal products, arguing that (i) the rule’s method of
5 restricting consumer use is arbitrary and capricious because of its incidental
6 impact on commercial uses of methylene chloride and (ii) it is unsupported
7 by substantial evidence because EPA failed to adequately consider the costs
8 of the Proposed Rule. A group of Environmental Petitioners also challenges
9 the rule, contending that the Toxic Substances Control Act, 15 U.S.C. § 2601, *et*
10 *seq.* (“TSCA”) required the EPA to regulate commercial uses of methylene
11 chloride as well as consumer uses. Held, (a) HSIA’s challenge to the Final
12 Rule fails because the Final Rule was supported by substantial evidence; (ii)
13 the Environmental Petitioners’ challenge is prudentially unripe for review at
14 this time. The petitions for review of the Final Rule are DENIED.

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13 LEVAL, *Circuit Judge:*

14 This case involves two petitions for review of a Final Rule of the United
15 States Environmental Protection Agency (“EPA”). The rule restricts consumer
16 uses of methylene chloride, a chemical used in paint removal products, by
17 prohibiting the distribution of products containing methylene chloride to and
18 by retailers. Petitioner Halogenated Solvents Industry Alliance, Inc., (“HSIA”)
19 contends that the Final Rule’s undertaking to prevent consumer use of the
20 chemical by banning retail distribution should be set aside (1) because in
21 addition to *consumer* uses targeted by the Final Rule, that prohibition on
22 retailers incidentally also restricts *commercial* uses by small businesses, which
23 frequently purchase methylene chloride from retailers because their needs are
24 for smaller quantities; and (2) because EPA gave inadequate consideration to

1 costs imposed by the rule. Petitioners Labor Council for Latin American
2 Advancement; Natural Resources Defense Council, Inc.; Vermont Public
3 Interest Research Group; Safer Chemicals Healthy Families; Lauren Atkins;
4 and Wendy Hartley (collectively, “Environmental Petitioners”) contend that
5 the Toxic Substances Control Act, 15 U.S.C. § 2601, *et seq.* (“TSCA”) required
6 the EPA to regulate *commercial* uses of methylene chloride as well as *consumer*
7 uses, and that EPA’s failure to do so requires that the Final Rule be expanded
8 to encompass commercial uses.

9 In response to HSIA, EPA argues that TSCA required it to impose rules
10 that would ensure that the risks posed by consumer uses of methylene
11 chloride are “no longer present[ed],” 15 U.S.C. § 2605(a), and that the
12 consumer use restriction effectuated by prohibiting sales to and by retailers
13 was a reasonable means, supported by substantial evidence, of achieving this
14 end. In response to the Environmental Petitioners’ argument that commercial
15 uses of methylene chloride should also have been restricted, EPA argues that,
16 because it is still considering how to appropriately regulate commercial uses,
17 the agency’s action on this question is not yet final or subject to judicial
18 review.

1 We conclude that EPA’s implementation of a retailer distribution ban
2 was a reasonable means to achieve its required goal of ensuring that the risks
3 posed by consumer uses of methylene chloride were “no longer present[ed].”
4 15 U.S.C. § 2605(a). With respect to Environmental Petitioners’ claim
5 regarding regulation of commercial uses, we conclude that it is prudentially
6 unripe for judicial review at this time. Accordingly, the petitions for review of
7 the challenged Final Rule are DENIED.

8 BACKGROUND

9 I. Methylene Chloride and EPA’s Evaluation of its Risks

10 TSCA imposes a duty on EPA to “conduct risk evaluations . . . to
11 determine whether a chemical substance presents an unreasonable risk of
12 injury to health or the environment, without consideration of costs or other
13 nonrisk factors.” 15 U.S.C. § 2605(b)(4)(A). Under § 2605(a), if the
14 Administrator of EPA determines that a chemical “presents an unreasonable
15 risk of injury to health or the environment, the Administrator shall by rule . . .
16 [impose] requirements to such substance . . . to the extent necessary so that [it]
17 no longer presents such risk.” In this opinion, we refer to rules promulgated

1 by EPA under this section, such as the Final Rule that is the subject of the
2 Petitioners' challenge, as "§ 2605(a) rules."

3 Methylene chloride is a chemical used as a solvent with a variety of
4 commercial and consumer use applications, including as a component of
5 paint removal products. EPA first initiated a "comprehensive regulatory
6 investigation" of the risks posed and options to regulate methylene chloride
7 in 1985 but took little action with respect to that investigation until 2012. *See*
8 *Methylene Chloride; Initiation of Regulatory Investigation*, 50 Fed. Reg.
9 42,038 (Oct. 17, 1985). In February 2012, the Center for Disease Control and
10 Prevention ("CDC") issued a report identifying thirteen deaths from the use
11 of methylene chloride paint strippers in commercial bathtub refinishing. That
12 report noted that the widespread availability of such products—many of
13 which consisted of 60-90% methylene chloride—"puts both professional
14 bathtub refinishers and do-it-yourselfers at risk." Joint App'x 39.

15 In June 2012 (prior to TSCA's amendment in 2016), EPA included
16 methylene chloride on its TSCA Work Plan, a list of chemicals that EPA
17 planned to assess under TSCA. EPA produced a draft risk assessment of
18 methylene chloride's paint stripping uses in January 2013 and finalized the

1 risk assessment in August 2014 (hereafter “2014 Risk Assessment”). The 2014
2 Risk Assessment identified numerous risks arising from the use of paint
3 strippers containing methylene chloride, including risks of acute exposure
4 causing “death; neurological impacts such as coma, incapacitation, loss of
5 consciousness, and dizziness; and liver effects,” and risks of chronic exposure
6 causing “brain cancer, liver cancer, non-Hodgkin lymphoma, and multiple
7 myeloma.” Methylene Chloride and N-Methylpyrrolidone; Regulation of
8 Certain Uses Under TSCA Section 6(a), 82 Fed. Reg. 7,464, 7,468, 7,471
9 (proposed Jan. 19, 2017) (hereafter “Proposed Rule”). The 2014 Risk
10 Assessment, though noting these risks, was, as EPA points out, “a scientific
11 document,” which “[a]t no point . . . purport[ed] to make a policy-based
12 determination that the identified risks were ‘unreasonable risks’ under
13 [Section] 2605(a).” EPA Br. 10; *see also* Joint App’x 169-70. Still, there was
14 evidence in the 2014 Risk Assessment that persons engaged in bathtub
15 refinishing using products containing less than 85% methylene chloride were
16 exposed to concentrations of methylene chloride at levels characterized as
17 “Immediately Dangerous to Life and Health,” and that 49 deaths had been

1 caused by methylene chloride since 1976. EPA took no action to characterize
2 these risks as “unreasonable” under § 2605(a) until 2017.

3 **II. The 2017 Proposed Rule**

4 In 2017, EPA proposed a § 2605(a) rule regarding commercial and
5 consumer uses of methylene chloride in paint and coating removal. *See* 2017
6 Proposed Rule, 82 Fed. Reg. 7,464. The Proposed Rule was an exercise of the
7 EPA’s discretionary authority under 15 U.S.C. § 2625(l)(4), which permits
8 promulgation of § 2605(a) rules for chemicals, such as methylene chloride, for
9 which EPA had “published a completed risk assessment prior to June 22,
10 2016.” 15 U.S.C. § 2625(l)(4). Relying on the 2014 Risk Assessment, EPA
11 proposed to determine that both acute and chronic “methylene chloride
12 exposures during paint and coating removal present unreasonable risks.”
13 2017 Proposed Rule, 82 Fed. Reg. at 7,478. Accordingly, EPA proposed to
14 “prohibit the manufacture (including import), processing, and distribution in
15 commerce of methylene chloride for all consumer and for most types of
16 commercial paint and coating removal uses,” and “to prohibit the use of
17 methylene chloride for commercial paint and coating removal in [several]
18 specified sectors.” *Id.* at 7,465. EPA did not propose to “regulate the use of

1 methylene chloride in commercial furniture refinishing . . . or refinishing
2 conducted by professionals or commercial workers,” but noted that it
3 “intend[ed] to issue a separate proposal on methylene chloride in paint and
4 coating removal in commercial furniture refinishing” and that it “plan[ned] to
5 issue one final rule covering both this proposal and the future proposed rule
6 on methylene chloride in paint and coating removal in commercial furniture
7 refinishing.” *Id.* Finally, the EPA proposed to require that any products
8 containing methylene chloride intended for paint removal be distributed in
9 containers not less than 55 gallons and to require certain downstream
10 notification requirements regarding the prohibition against manufacturing
11 and distribution. *Id.* These notification requirements would apply only to
12 “manufacturers . . . , processors, and distributors” and not “retailers”; the
13 Proposed Rule defined “retailer” as “a person or business who distributes in
14 commerce a chemical substance, mixture, or article to consumer end users.”
15 *Id.* at 7,526, 7,529.

16 The Proposed Rule considered several regulatory alternatives to the
17 distribution ban and container-size restrictions:

1 First, it considered whether the unreasonable risk could be eliminated
2 by warning labels; it concluded that “[p]resenting information about
3 methylene chloride on a product label would not adequately address the
4 unreasonable risk . . . because the nature of the information the user would
5 need to read, understand, and act upon is extremely complex.” *Id.* at 7,474.
6 Though EPA “reason[ed] that revised labeling w[ould] not address the
7 unreasonable risk presented by methylene chloride in paint and coating
8 removal,” it sought public comments on “enhanced labeling requirements for
9 consumer paint and coating removal products containing methylene
10 chloride” based on recommendations from the Small Business Advocacy
11 Review (“SBAR”) Panel. *Id.*

12 Second, EPA considered regulations requiring the use of respirators,
13 but found that “[a]cute risks of incapacitation, coma, or death in workers
14 exposed to methylene chloride . . . are present even when respiratory
15 protection is used” “[i]n some industries with high exposure scenarios,” *id.* at
16 7,471, and that “not all workers may be able to wear respirators,” *id.* at 7,481.

17 Third, EPA considered regulating consumer and commercial uses of
18 methylene chloride separately, but found that products containing methylene

1 chloride “cannot be straightforwardly restricted to a single type of project or
2 user.” *Id.* at 7,479.

3 Fourth, EPA conducted a “limited evaluation” of a “training and
4 certification program for commercial paint and coating removers” as
5 recommended by the SBAR, but found that “effective risk reduction from
6 commercial use . . . would require additional regulation of distributors of
7 these products” to “ensur[e] that only trained and certified commercial users
8 are able to access these paint and coating removal products,” which the EPA
9 viewed “as a significant limitation for this approach.” *Id.* at 7,474. The EPA
10 sought public comment “on the feasibility of such a program.” *Id.*

11 EPA received tens of thousands of comments in response to the 2017
12 Proposed Rule (many the result of mass-mailing campaigns). A substantial
13 majority of those comments supported the Proposed Rule and determination
14 that the use of methylene chloride in both consumer and commercial paint
15 stripping posed an unreasonable risk of injury to health. EPA also received a
16 comment from the SBAR Panel, which recommended, as an alternative to a
17 distribution ban, a training and certification program for commercial uses of
18 products containing methylene chloride. The SBAR report included

1 comments from Small Entity Representatives (“SERs”) claiming that EPA had
2 underestimated the cost of reformulating products containing methylene
3 chloride and that increased costs would cause small entities to go out of
4 business. The Small Business Administration urged the EPA to “take back the
5 rule” or, alternatively, to “reassess the viability and technical feasibility of the
6 available alternatives, reevaluate the costs to formulators, and eliminate the
7 restriction on the container size for these chemical products.” Joint App’x 720.
8 The Department of Defense submitted comments urging EPA to adopt an
9 approach that would restrict access to methylene chloride by consumers
10 while still making it available in industrial settings. And in 2018, after the
11 comment period had ended, Petitioner HSIA submitted a white paper to the
12 Small Business Administration recommending that EPA consider a training,
13 certification, and limited access program for commercial uses.

14 **III. The Challenged Final Rule**

15 On March 27, 2019, EPA promulgated the final rule at issue in this
16 appeal. Methylene Chloride; Regulation of Paint and Coating Removal for
17 Consumer Use Under TSCA Section 6(a), 84 Fed. Reg. 11,420 (Mar. 27, 2019)
18 (hereafter “Final Rule”). The Final Rule set forth a determination by EPA that

1 “the use of methylene chloride in *consumer* paint and coating removal
2 presents an unreasonable risk of injury to health due to acute human
3 lethality,” *id.* at 11,421 (emphasis added); on the other hand, it did not make a
4 final determination—as it had proposed to do—that *commercial* uses posed an
5 unreasonable risk. Instead, EPA published, on the same day, an Advanced
6 Notice of Proposed Rule Making (“2019 ANPRM”) “on questions related to a
7 potential training, certification, and limited access program as an option for
8 risk management for all of the commercial uses of methylene chloride in paint
9 and coating removal.” *Id.*; *see also* Methylene Chloride; Commercial Paint and
10 Coating Removal Training, Certification and Limited Access Program, 84 Fed.
11 Reg. 11,466 (Mar. 27, 2019) (hereafter “2019 ANPRM”).

12 To ensure that consumer uses of products containing methylene
13 chloride would “no longer present[]” the identified unreasonable risk in
14 consumer products, the Final Rule prohibited the “manufacturing, processing
15 and distributing in commerce methylene chloride for consumer paint and
16 coating removal” and prohibited the distribution in commerce of methylene
17 chloride (or products containing it) both to and by “retailers.” 2019 Final Rule,
18 84 Fed. Reg. at 11,435. The Final Rule defined “retailer” as:

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

9 *Id.*

10 EPA considered and rejected a restriction on the distribution of
11 methylene chloride paint strippers in containers with a volume less than 55
12 gallons along with downstream notification requirements, which it
13 characterized as the “primary alternative regulatory action.” *Id.* at 11,427. It
14 determined that the ban on sales to and by retailers was more cost effective
15 than the container-size restriction because it “achieve[d] the necessary risk
16 reduction . . . with estimated lower costs” than the container-size restriction,
17 which would have caused costs to be “higher due to the cost of compliance
18 with the container volume requirements which impact commercial users not
19 targeted by the rule.” *Id.*

20 As noted above, the Final Rule did not undertake to regulate
21 commercial uses of methylene chloride, nor did it determine that such uses
22 present an unreasonable risk of injury to health or the environment. Instead, it

1 proposed in the 2019 ANPRM that a training and certification program,
2 combined with limited access by commercial users, “could allow access to
3 paint and coating removal products containing methylene chloride only to
4 commercial users who are certified as properly trained to engage in use
5 practices that do not present unreasonable risks.” 2019 ANPRM, 84 Fed. Reg.
6 at 11,466. Though the 2017 Proposed Rule had already sought comments on
7 such a program, EPA received only one responsive comment, from the
8 Environmental Defense Fund, which was sharply critical. *Id.* at 11,468. But, as
9 previously noted, in 2018, following the close of the comment period, HSIA
10 submitted a white paper advocating for such a training and certification
11 program. *Id.* EPA noted that such a program was similar to one used in the
12 United Kingdom, where access to methylene chloride is restricted to certified
13 commercial end users, while unobtainable by consumer end users. *Id.* at
14 11,469.

15 On April 18, 2019, Environmental Petitioners filed their petition in this
16 court for review of the Final Rule. On May 24, 2019, HSIA filed its petition for
17 review of the Final Rule in the D.C. Circuit, which granted EPA’s motion to

1 transfer the petition to this court. On August 21, 2019, this court consolidated
2 the cases into this appeal.

3 **DISCUSSION**

4 **I. The Toxic Substances Control Act (“TSCA”) and its Application to EPA’s**
5 **Evaluations and Regulations of Methylene Chloride**

6 TSCA, originally enacted in 1976, was intended “to prevent
7 unreasonable risks of injury to health or the environment associated with the
8 manufacture, processing, distribution in commerce, use, or disposal of
9 chemical substances.” S. Rep. No. 94-698, at 1 (1976), *as reprinted in* 1976
10 U.S.C.C.A.N. 4491, and to give EPA “adequate authority . . . to regulate
11 chemical substances and mixtures which present an unreasonable risk of
12 injury to health or the environment.” 15 U.S.C. § 2601(b)(2).

13 The nature of EPA’s duties and powers under TSCA has changed over
14 time. Prior to 2016, § 2605 did not prescribe procedures for conducting
15 chemical risk evaluations, the initiation of which was within EPA’s discretion,
16 and the EPA had identified very few chemicals subject to § 2605(a)’s mandate.
17 If chemicals were determined, prior to 2016, to present an unreasonable risk
18 of injury to health or the environment, TSCA required the EPA to regulate
19 them only to the extent necessary “to protect *adequately* against such risk” and

1 in so regulating to use “the least burdensome requirements,” § 2605(a) (2012)
2 (emphasis added) (amended 2016), which some courts interpreted to require
3 the EPA to balance the economic costs of proposed regulatory restrictions
4 against the environmental benefits those restrictions would provide, *see, e.g.,*
5 *Corrosion Proof Fittings v. EPA*, 947 F.2d 1201, 1215 (5th Cir. 1991).

6 The 2016 amendments to TSCA substantially increased EPA’s
7 obligation to evaluate and regulate dangerous chemicals. Instead of leaving
8 the completion of risk evaluations to EPA’s discretion, TSCA now requires
9 the EPA to conduct risk assessments for a minimum number of chemicals,
10 subject to statutory deadlines. 15 U.S.C. §§ 2605(b)(2)(A), (b)(1)(B)(i), (b)(4)(D).
11 It also prescribes detailed requirements for these chemical risk evaluations,
12 including that the determination whether a chemical presents an
13 unreasonable risk of injury to health or the environment shall be reached
14 “without consideration of costs or other nonrisk factors.” § 2605(b)(4)(A). And
15 it imposes statutory deadlines for regulation of a chemical found to present
16 an unreasonable risk of injury to health or the environment under any of its
17 conditions of use. For such chemicals, the amended statute requires EPA to
18 propose a risk management rule within one year, and finalize that rule within

1 two years, subject to a possible two-year extension provided certain
2 conditions are met. § 2605(c)(1).

3 The amended statute also requires more stringent regulation of
4 chemicals identified as posing an unreasonable risk, replacing the previous
5 mandate “to protect adequately” against identified unreasonable risks with
6 an obligation to regulate the substance “to the extent necessary so that [it] *no*
7 *longer presents* such risk.” Compare § 2605(a) (2012) (amended 2016), *with*
8 § 2605(a) (2018) (current) (emphasis added). And the statute no longer
9 requires EPA to adopt the “least burdensome requirements” when regulating
10 chemicals that pose an unreasonable risk to health or the environment.

11 This does not mean that the EPA is free to ignore costs of regulating
12 such chemicals. When promulgating a rule under § 2605(a), as amended, EPA
13 must still “factor in, to the extent practicable,” several considerations,
14 including the “effects of the chemical . . . on the environment,” “the benefits
15 of the chemical . . . for various uses,” and “the reasonably ascertainable
16 economic consequences of the rule.” § 2605(c)(2)(A)-(B). The “factor[ing] in”
17 of reasonably ascertainable economic consequences includes consideration of
18 “the costs and benefits of the proposed and final regulatory actions and of the

1 1 or more primary alternative regulatory actions considered by the
2 Administrator.” § 2605(c)(2)(A)(iv). “[I]n deciding whether to prohibit or
3 restrict in a manner that substantially prevents a specific condition of use of a
4 chemical substance or mixture . . . [EPA] shall consider, to the extent
5 practicable, whether technically and economically feasible alternatives that
6 benefit health or the environment, compared to the use so proposed to be
7 prohibited or restricted, will be reasonably available as a substitute when the
8 proposed prohibition or other restriction takes effect.” § 2605(c)(2)(C). EPA’s
9 duty to consider costs, as contemplated by these statutory provisions, is
10 subject to the overall mandate to regulate the chemical to the extent that it “no
11 longer presents” the identified unreasonable risk. § 2605(a).

12 Shortly prior to the 2016 amendment, EPA had completed risk
13 evaluations for several chemicals, including methylene chloride. TSCA’s
14 amendment addressed such “chemical substance[s] . . . for which the
15 Administrator has published a completed risk assessment prior to June 22,
16 2016.” § 2625(l)(4). Rather than requiring EPA to re-complete risk assessments
17 for these chemicals, the 2016 amendment provides that “the Administrator
18 may publish proposed and final rules under section 2605(a) of this title that

1 are consistent with the scope of the completed risk assessment for the
2 chemical substance and consistent with other applicable requirements of
3 section 2605 of this title.” *Id.*

4 Because § 2625(l)(4) provides that EPA “may” publish and propose
5 § 2605(a) rules regarding chemicals for which EPA had already completed a
6 risk assessment, EPA’s decision, based on the 2014 Risk Assessment,
7 regarding whether to determine that consumer and commercial uses of
8 methylene chloride pose an unreasonable risk was not subject to the same
9 statutory deadlines as the same decision would be if based on a risk
10 evaluation completed after TSCA’s amendment. However, in 2016, EPA
11 designated methylene chloride as one of ten chemicals that would be the
12 subject of its required initial risk evaluation under the 2016 TSCA
13 amendment. After the 2019 Final Rule and ANPRM, EPA published a draft
14 risk evaluation for methylene chloride that included its use in commercial
15 paint and coating removal. That draft risk evaluation proposed to find that
16 such commercial use presents an unreasonable risk of injury to health.
17 Because this new risk evaluation—unlike the 2014 Risk Assessment—was
18 undertaken in compliance with the 2016 Amendment, it is subject to the

1 statutory deadlines requiring the risk evaluation to be finalized by June 2020.
2 § 2605(b)(4)(G). On June 24, 2020, consistent with this statutory deadline, EPA
3 finalized this risk evaluation, determining that commercial use of methylene
4 chloride in paint and coating removal presents an unreasonable risk of injury
5 to health. Methylene Chloride (MC); Final Toxic Substances Control Act
6 (TSCA) Risk Evaluation; Notice of Availability (“2020 Final Risk Evaluation”),
7 85 Fed. Reg. 37,942. Under § 2605(c)(1)(B), EPA must finalize a § 2605(a) risk
8 management rule regarding these identified commercial uses within two
9 years of the publication of the 2020 Final Risk Evaluation, subject to extension
10 under § 2605(c)(1)(C).

11 **II. Standard of Review**

12 For judicial review of rules promulgated by EPA under § 2605(a), TSCA
13 provides a standard worded slightly differently from the standard established
14 by § 706 of the Administrative Procedure Act (“APA”). The APA’s standard
15 of review provides that reviewing courts shall set aside agency action that is
16 “unsupported by substantial evidence.” 5 U.S.C. § 706(2)(E). “Substantial
17 evidence” under the APA has been understood to mean “such relevant
18 evidence as a reasonable mind might accept as adequate to support a

1 conclusion." *Universal Camera Corp. v. NLRB*, 340 U.S. 474, 477 (1951). Under
2 that standard, a court will not set aside an agency's action so long as it is
3 "supported by less than a preponderance but more than a scintilla of
4 evidence." *Sprint Spectrum L.P. v. Willoth*, 176 F.3d 630, 638 (2d Cir. 1999)
5 (internal quotation marks omitted). "Substantial evidence [under the APA]
6 requires 'something less than the weight of the evidence, and the possibility
7 of drawing two inconsistent conclusions from the evidence does not prevent
8 an administrative agency's finding from being supported by substantial
9 evidence.'" *Corrosion Proof*, 947 F.2d at 1213 (quoting *Consolo v. Federal*
10 *Maritime Comm'n*, 383 U.S. 607, 620 (1966)).

11 In contrast, § 2618(c)(1)(B) of TSCA provides, "[I]n the case of review
12 of . . . a rule under section . . . 2605(a) (including review of the associated
13 determination [of unreasonable risk]), . . . the standard of review prescribed
14 by [APA § 706(2)(E)] shall not apply and the court shall hold unlawful and set
15 aside such rule if the court finds that the rule is not supported by substantial
16 evidence in the rulemaking record taken as a whole." 15 U.S.C.
17 § 2618(c)(1)(B).

1 Upon a straightforward reading of the text of these two provisions, it is
2 not clear how the different wordings change the standard. The D.C. Circuit
3 has sensibly observed that “Congress apparently contemplated that the TSCA
4 standard should be viewed as a distinct standard; otherwise there would
5 have been no need to specifically rule out the APA review standard.” *Chem.*
6 *Mfrs. Ass’n v. EPA*, 859 F.2d 977, 991 (D.C. Cir. 1988). Relying on TSCA’s
7 legislative history, that court held that TSCA’s substantial evidence standard
8 requires “more searching [review] than the judicial review undertaken in
9 most agency cases.” *Id.* at 992. The Third and Fifth Circuits have reached
10 similar conclusions. *See Ausimont U.S.A. Inc. v. EPA*, 838 F.2d 93, 96 (3d Cir.
11 1988); *Shell Chemical Co. v. EPA*, 826 F.2d 295, 297 (5th Cir. 1987). Those courts
12 have asserted that the TSCA “substantial evidence” standard is a
13 “particularly demanding one,” as compared to the arbitrary and capricious
14 standard. *Chem. Mfrs.*, 859 F.2d at 992 (internal quotation marks omitted). We
15 agree with those circuits that TSCA’s “substantial evidence” standard is more

1 demanding on the agency than the standard of review otherwise prescribed
2 by the APA.¹

3 While we agree with the D.C. Circuit that Congress's emphasis on the
4 fact that the standard of TSCA differs from the APA standard surely means
5 that Congress intended the two standards to be different, we find no need in
6 this case to reach a conclusion on the extent of the difference. Whether EPA's
7 Final Rule is evaluated under a standard akin to APA's substantial evidence
8 review or under a "more searching" TSCA substantial evidence standard

¹ Environmental Petitioners insist that APA's "arbitrary and capricious" standard of review survives TSCA's statutory displacement of APA's "substantial evidence" standard. EPA, in response, argues that Environmental Petitioners' argument is "technically incorrect" but that the difference between the arbitrary and capricious standard and the substantial evidence standard is "largely semantic," relying on *Ass'n of Data Processing Serv. Orgs., Inc. v. Bd. of Governors of Fed. Rsrv. Sys.*, 745 F.2d 677, 683-85 (D.C. Cir. 1984) ("*ADPSCO*"). We find neither argument persuasive. *ADPSCO* interpreted APA § 706(2)(E)'s "substantial evidence" standard, not TSCA's "substantial evidence" standard, and, as noted above, the D.C. Circuit has since concluded that these standards are distinct. *Chem. Mfrs.*, 859 F.2d at 991. Courts that have considered the question have rejected the survival of "arbitrary and capricious" review of TSCA rules, concluding instead that TSCA's substantial evidence standard is "particularly demanding." *See, e.g., id.*, 859 F.2d at 991 ("Congress perceived some difference between the standard it chose for TSCA and the APA's arbitrary-and-capricious standard."); *see also Corrosion Proof*, 947 F.2d at 1214 ("Congress put the substantial evidence test in the statute because it wanted the courts to scrutinize the Commission's actions more closely than an 'arbitrary and capricious' standard would allow." (internal quotation marks omitted)).

1 adopted by other circuits, for the reasons described below, we conclude that
2 the Final Rule is adequately supported by substantial evidence in the
3 rulemaking record taken as a whole, and should not be set aside.

4 **III. HSIA's Challenge to the 2019 Final Rule**

5 HSIA challenges the 2019 Final Rule on four grounds. It argues: (1) the
6 prohibition of sales to and by retailers was inconsistent with the EPA's intent
7 to allow commercial uses, because many commercial users purchase products
8 containing methylene chloride products through retailers; (2) EPA provided
9 insufficient notice and opportunity to comment on the definition of "retailer"
10 in the final rule; (3) EPA's assessment of the Final Rule's impact on methylene
11 chloride product formulators was inadequate; and (4) EPA lacked substantial
12 evidence to support its prohibition on distribution to and by retailers. We
13 reject HSIA's arguments.

14 *1. The prohibition on sales of methylene chloride products to and by retailers is*
15 *not inconsistent with EPA's stated policy.*

16 HSIA argues that the incidental effect on commercial users of the Final
17 Rule's ban on sales to or by retailers is inconsistent with EPA's stated policy
18 of allowing continued access to methylene chloride products by commercial
19 users. HSIA points out that retail outlets are an important source of supply

1 for commercial users that use only modest quantities of products containing
2 methylene chloride. HSIA further argues that the retailer ban is inconsistent
3 with EPA's reasoning for rejecting the 55-gallon minimum container
4 restriction, which EPA based on the restriction's potential impact on small
5 commercial users who typically purchase methylene chloride products in
6 smaller quantities.

7 The first of these arguments is fundamentally flawed because it rests on
8 the mistaken premise that the Final Rule espoused a policy favoring
9 continued access to methylene chloride by commercial users. While it is true
10 that commercial uses were not "targeted by the rule," 84 Fed. Reg. at 11,427,
11 neither did the Final Rule state or imply a policy encouraging, supporting, or
12 even approving the continuation of commercial uses. To the contrary, the
13 promulgation of the Final Rule in 2019 intentionally left open and under
14 consideration the questions whether and how to regulate commercial uses.
15 EPA subsequently reached a determination that commercial uses of
16 methylene chloride products present an unreasonable risk of injury to health,
17 triggering the statutory timeline for finalizing a § 2605(a) rule in the near
18 future. The Final Rule's incidental effect on commercial users' ability to access

1 methylene chloride products could not be inconsistent with EPA's policy of
2 allowing such access because the EPA had established no such policy.

3 Nor does the Final Rule prevent commercial users from obtaining
4 methylene chloride products, although it may cause some commercial users
5 to seek different sources from those that they used in the past. EPA
6 considered this very possibility, noting that the Final Rule "potentially creates
7 a new marketplace for wholesalers and they may now sell these products to
8 commercial users who previously purchased from retail stores," and that,
9 although currently "[w]holesalers tend not to sell products in smaller
10 quantities, . . . with the change in the marketplace, [they] may choose to do so
11 if such an action would be profitable." Joint App'x 1023. EPA's rejection of the
12 55-gallon minimum container restriction, rather than being inconsistent with
13 its adoption of the retailer ban, supports the possibility of this evolving
14 marketplace by allowing continued wholesale distribution of methylene
15 chloride products in smaller units to replace the sales previously made by
16 retailers to commercial users of smaller quantities.

1 2. *The definition of retailer in the Final Rule was a “logical outgrowth” of the*
2 *Proposed Rule, and so gave sufficient notice and opportunity to comment.*

3 HSIA contends that EPA provided insufficient notice and opportunity
4 to comment on the definition of “retailer” in the final rule. EPA was required
5 to provide notice of “either the terms or substance of the proposed rule *or a*
6 *description of the subjects and issues involved.*” 5 U.S.C. § 553(b)(3) (emphasis
7 added); *see* 15 U.S.C. § 2605(c)(3) (noting that 5 U.S.C. § 553 applies to
8 § 2605(a) rules). “Courts of Appeals have generally interpreted this to mean
9 that the final rule the agency adopts must be a logical outgrowth of the rule
10 proposed.” *Long Island Care at Home, Ltd. v. Coke*, 551 U.S. 158, 174 (2007)
11 (internal quotation marks omitted); *see also Nat’l Black Media Coal v. FCC*, 791
12 F.2d 1016, 1022 (2d Cir. 1986). Accordingly, “a final rule need not be an exact
13 replica of the rule proposed in the Notice,” *Nat’l Black Media*, 791 F.2d at 1022,
14 and the standard is generally satisfied if the notice given by the agency fairly
15 apprises interested persons of the subjects and issues that will be resolved by
16 the adoption of a final rule. *See Riverkeeper, Inc. v. EPA*, 475 F.3d 83, 113 (2d
17 Cir. 2007), *rev’d on other grounds sub nom. Entergy Corp. v. Riverkeeper, Inc.*, 556
18 U.S. 208 (2009). We have explained that “an agency may modify a rule
19 through the notice-and-comment process so long as the agency’s modification

1 is rational and ‘the agency’s path may reasonably be discerned.’” *Cooling*
2 *Water Intake Structure Coal. v. EPA*, 905 F.3d 49, 71 (2d Cir. 2018) (quoting
3 *Motor Vehicle Mfrs. Ass’n of the U.S., Inc. v. State Farm*, 463 U.S. 29, 43 (1983)).
4 TSCA additionally requires EPA to “publish a notice of proposed rulemaking
5 stating with particularity the reason for the proposed rule.” 15 U.S.C.
6 § 2605(c)(3)(A).

7 HSIA argues (1) that EPA’s retailer ban is not a “logical outgrowth” of
8 the Proposed Rule because the retailer ban is inconsistent with the proposed
9 55-gallon restriction, which would have allowed at least some sales to and by
10 retailers, as well as with the Proposed Rule’s carveout for furniture
11 refinishers; and (2) that, given the change in text and purpose of the definition
12 of retailer as between the Proposed Rule and the Final Rule, EPA gave
13 inadequate notice. In support of this argument, HSIA contends that “despite
14 the enormous number of comments in the record, not a single commenter
15 addressed a ban on sales to or by retailers,” though some commenters
16 opposed bans on sales for commercial use.

17 We reject HSIA’s argument. We find that EPA satisfied the “logical
18 outgrowth” standard as we have interpreted it and complied with TSCA’s

1 additional procedural requirements with respect to notice. EPA’s extensive
2 descriptions of the health risks posed by methylene chloride, which the Final
3 Rule seeks to eliminate in the consumer use context, plainly satisfied the
4 requirement that it “state with particularity the reason” for the proposed
5 regulation. The Proposed Rule made clear that the EPA was considering
6 prohibiting “the manufacture (including import), processing, and distribution
7 in commerce of methylene chloride for consumer and most types of
8 commercial paint and coating removal.” 82 Fed. Reg. at 7,464. And the
9 Proposed Rule described the difficulty of entirely disentangling regulation of
10 consumer uses from regulation of commercial uses, given that “paint and
11 coating removal products containing methylene chloride frequently are
12 available in the same distribution channels to consumers and professional
13 users” and “cannot be straightforwardly restricted to a single type of project
14 or user.” *Id.* at 7,479, 7,505. In other words, the Final Rule, which restricts
15 distribution of methylene chloride paint removal products *only* in commercial
16 channels that reach consumers, is considerably less restrictive than the
17 regulation considered by the Proposed Rule, and its incidental impact on
18 commercial users reflects the difficulty of disentangling consumer and

1 commercial uses described by the Proposed Rule. Indeed, commercial users
2 have considerably greater access to methylene chloride products under the
3 Final Rule than they would have had under the regulation considered by the
4 Proposed Rule.

5 EPA gave notice that it was contemplating a rule that would drastically
6 reduce or even eliminate access to certain products containing methylene
7 chloride. The restriction ultimately adopted in the Final Rule was
8 considerably less extreme than the contemplated restriction announced in the
9 Proposed Rule. Interested parties had an opportunity to comment not only on
10 the more extreme level of restriction that would have resulted from adoption
11 of the Proposed Rule, but also on less extreme restrictions the agency might
12 settle on within the scope of the proposed restrictions announced.

13 Acceptance of HSIA's concept of the notice and comment obligation
14 would substantially freeze EPA's consideration of the Final Rule to an "all or
15 nothing" choice of adopting or categorically rejecting exactly what was
16 originally proposed. It would unreasonably encumber and delay agency
17 action, forcing the agency to choose between ignoring commentary
18 suggesting useful modifications of proposed rules, or endlessly delaying

1 action until submitted commentary and further study failed to suggest any
2 desirable modification. Such an interpretation of the notice and comment
3 requirement would seriously harm the ability of agencies to deal flexibly with
4 pressing problems. More importantly, such an interpretation would be
5 plainly inconsistent with the statutory standard requiring that the “notice of
6 proposed rulemaking . . . include . . . either the terms or substance of the
7 proposed rule *or a description of the subjects and issues involved.*” 5 U.S.C.
8 § 553(b)(3).

9 We conclude that EPA complied with its notice and comment
10 obligations and that the Final Rule was a logical outgrowth of its originally
11 noticed proposal.

12 3. *EPA adequately considered costs to formulators of methylene chloride.*

13 HSIA next argues that EPA failed to consider adequately the impact of
14 the Final Rule on formulators of products containing methylene chloride. We
15 disagree.

16 EPA estimated that the cost resulting from the Final Rule to formulators
17 who would have to develop a new line of products not containing methylene
18 chloride would be approximately \$27,000 annualized over two decades. This

1 estimate was extrapolated from a survey addressing the manufacturing
2 marketspace for similar products in Canada, and an additional survey
3 regarding another chemical, trichloroethylene (also known as “TCE”), which
4 EPA used to confirm the applicability for a U.S. rulemaking of the first
5 survey’s study of a Canadian market. And EPA found that there are
6 “technically and economically feasible chemical substitutes or alternative
7 methods that are reasonably available to a consumer for almost every
8 situation in which methylene chloride is used to remove paints or coatings.”
9 2019 Final Rule, 84 Fed. Reg. at 11,427-28.

10 HSIA argues that this evidence was insufficient to support EPA’s
11 determination regarding the costs to formulators resulting from the Final
12 Rule and that it was undermined by three comments submitted in response to
13 the Proposed Rule. First, HSIA claims that the American Chemistry Council
14 informed EPA that the surveys on which it relied were not valid because
15 “replacing methylene chloride is a substantially different undertaking from
16 replacing [TCE].” HSIA Br. 43. But HSIA’s citation in support of its assertion
17 points to a comment of the American Chemistry Council that says nothing of
18 the sort. The comment “recommends that EPA provide fuller discussion that

1 explains why these [surveys] are appropriate to include in the costs
2 calculation,” but does not assert that the surveys were inadequate. Joint
3 App’x 760. Second, HSIA points to a comment from a small business
4 formulator who stated that 40% of its revenue was derived from methylene
5 chloride products and that a 55-gallon container restriction could result in the
6 loss of its business. But neither of these concerns undermine EPA’s calculation
7 of costs; under the Final Rule, the commenter is still able to formulate
8 methylene chloride products for distributors that exclusively serve
9 commercial users, to develop alternative products, and to continue packaging
10 its products in containers smaller than 55 gallons. Finally, HSIA relies on a
11 comment from the SBA claiming that product lines would “disappear”
12 because “there are no drop-in replacements for methylene chloride.” Joint
13 App’x 718-19. But, again, formulators are not prevented from developing
14 methylene chloride products for distribution to commercial users or for uses
15 other than paint and coating removers, and the EPA found evidence that
16 alternatives are economically and technically feasible, as indicated in part by
17 many retailers that, even prior to being required to do so by the Final Rule,

1 announced that they were voluntarily discontinuing the sale of methylene
2 chloride products.

3 In sum, the comments on which HSIA relies do not demonstrate that
4 EPA's estimation of costs to formulators was inadequate, in large part
5 because those comments are based on the faulty premise that formulators can
6 no longer manufacture methylene chloride products—the Final Rule does not
7 prohibit manufacturing methylene chloride for commercial paint-stripping
8 uses or for certain non-paint-stripping uses. Record evidence reasonably
9 supports the conclusion that EPA considered the reasonably ascertainable
10 consequences of the Final Rule on formulators, as well as EPA's quantitative
11 and qualitative conclusions regarding those consequences. In any event,
12 HSIA's argument seems to assume that EPA is compelled to accept every
13 submitted comment as accurate and reconcile its ultimate rule to every such
14 comment. The requirement to produce a rule that is "supported by
15 substantial evidence in the rulemaking record taken as a whole," 15 U.S.C.
16 § 2618(c)(1)(B), does not impose an obligation to reconcile the rule with every
17 comment submitted, much less to accept the validity of every such comment.
18 HSIA has failed to demonstrate that EPA's estimation of the costs to

1 formulators of methylene chloride products is not supported by substantial
2 evidence.

3 *4. EPA adequately considered the costs to retailers and distributors of*
4 *methylene chloride products.*

5 Finally, HSIA argues that EPA failed to account adequately for the costs
6 to retailers of its prohibition of sales to and by retailers of methylene chloride
7 paint stripping products. It is true that costs to retailers were not estimated in
8 the EPA's economic analysis of the Final Rule. EPA explained that this was
9 "because the potential cost impact on retailers is uncertain," and that "costs to
10 retailers were not estimated because of these uncertainties, and this may
11 represent a category of costs that are excluded from the analysis." Joint App'x
12 957, 1005. HSIA argues that these statements should be deemed a refusal by
13 the EPA to consider the costs to retailers. HSIA further argues that the EPA
14 failed to consider adequately the costs of its retail ban on distributors (who
15 would otherwise sell to retailers) and the cost to small commercial users from
16 the elimination of an important portion of their supply chain. The failure to
17 consider these costs, HSIA argues, was equivalent to EPA estimating the costs
18 to be zero. While HSIA acknowledges that the EPA need only rely on
19 "reasonably available information" and describe the "reasonably

1 ascertainable economic consequences” of the Final Rule, 15 U.S.C.
2 § 2605(c)(2)(A), it argues that EPA nonetheless cannot ignore a cost and that
3 EPA’s lack of information with respect to the retail ban’s costs was “its own
4 fault,” given the retail ban’s absence from the Proposed Rule, HSIA Br. at 52-
5 53. HSIA argues that, in contrast, EPA had extensive evidence of the costs that
6 would result from the 55-gallon container size restriction, because adequate
7 notice was provided of that restriction, permitting commenters to provide
8 such information.

9 We disagree that the EPA’s inability to quantify the costs of the Final
10 Rule to retailers, distributors, and small commercial users means that it
11 ignored those costs. The record rather shows that EPA found the costs
12 impossible to estimate because of the likely growth of a new marketplace for
13 commercial-only distribution and sales of alternative products. These
14 possibilities, the EPA reasoned, meant that the cost could potentially be
15 minimal, and that retailers “could be better off under the rule” if profit
16 margins on alternative products were higher. EPA Br. at 90 (collecting record
17 citations). For distributors, as previously discussed, *supra* 34-35, EPA
18 considered—though it could not quantify—costs to commercial end users; it

1 found that these costs were not likely to be significant because of the
2 availability of technically and economically feasible substitutes. *See* 2019 Final
3 Rule, 84 Fed. Reg. at 11,427-28. These available substitutes mean that
4 commercial end users who do not want to switch suppliers will have
5 substitute products available to them, and, in any event, will likely have
6 access to a new marketplace in which wholesalers distribute directly to
7 commercial users to meet the demand previously met by retailers.

8 These qualitative assessments of the costs to retailers, distributors, and
9 commercial end users were reasonable, unrebutted by record evidence, and
10 consistent with the EPA's obligation to consider "reasonably available
11 information" in estimating such costs. Based on the record before the EPA, it
12 was reasonable to conclude that, to the extent the Final Rule would result in
13 some lost business for these entities, it was also likely to create new business
14 via alternative products and an evolving marketplace. Far from ignoring
15 these potential consequences of the Final Rule, EPA considered them,
16 described them, and concluded that potential for new markets to replace the
17 losses initially caused by the Final Rule supported the rule's implementation.
18 Reasonable minds might have reached a different conclusion from the

1 evidence available to the EPA, but “the possibility of drawing two
2 inconsistent conclusions from the evidence does not prevent an
3 administrative agency’s finding from being supported by substantial
4 evidence.” *Corrosion Proof*, 947 F.2d at 1213 (quoting *Consolo*, 383 U.S. at 620).

5 * * *

6 In sum, having considered HSIA’s challenges to the Final Rule, we find
7 them unpersuasive. HSIA fails to demonstrate that EPA’s prohibition on sales
8 to and by retailers was not a reasonable means, supported by substantial
9 evidence, to ensure that the unreasonable risks of methylene chloride paint
10 removal products for consumer uses be “no longer present[ed].” § 2605(a).
11 We therefore deny HSIA’s petition to set aside the Final Rule.

12 **IV. Environmental Petitioners’ Challenge to the 2019 Final Rule**

13 Environmental Petitioners contend the 2019 Final Rule was defective by
14 reason of (i) EPA’s failure to determine that use of methylene chloride in
15 *commercial* paint and coating removal (as it determined for *consumer* uses)
16 “presents an unreasonable risk of injury to health or the environment,”
17 15 U.S.C. § 2605(a), as well as (ii) its failure to impose specific regulations
18 governing commercial use so as to remove the unreasonable risk. They

1 advance a forceful argument that, given years of scientific data revealing
2 significant risks of severe adverse health consequences, it was inescapable
3 that the chemical poses an unreasonable risk in commercial applications,
4 particularly in view of the fact that commercial workers characteristically
5 experience far higher degrees of exposure than consumers. Environmental
6 Petitioners point to a history of statements by EPA, prior to its adoption of the
7 Final Rule in 2019, acknowledging the significant health risks posed by
8 commercial uses of methylene chloride and EPA's corresponding statement of
9 its intention in the 2017 Proposed Rule to reach a risk determination as to
10 both consumer and commercial uses. Environmental Petitioners also advance
11 the far more ambitious and less forceful argument that, in adopting the 2019
12 Final Rule, EPA was required by law not only to make a conclusive risk
13 evaluation but also to finalize regulations, either banning or controlling
14 commercial uses so that the risk would be "no longer present[ed]," 15 U.S.C.
15 § 2605(a).

16 EPA, in response, contends it made a reasonable decision to defer
17 reaching a determination for commercial uses pending further study of
18 possibilities of controlling risks in a commercial setting. It also advances

1 several arguments that there should be no judicial review of its deliberations
2 on commercial uses until it reaches final determinations. Among those
3 arguments, it asserts that its consideration of commercial uses is prudentially
4 unripe for judicial review, as judicial review at this time would involve
5 “judicial interference [before] an administrative decision has been formalized
6 and its effects felt in a concrete way by the challenging parties,” *Abbott Labs. v.*
7 *Gardner*, 387 U.S. 136, 148-49 (1967), without substantial alleviation of
8 hardship to the petitioners. EPA points out that it has not procrastinated, nor
9 ignored the significant risks arising from commercial uses of methylene
10 chloride. It rather opted to begin with the easier task of developing a
11 regulatory scheme for consumer uses and then turning to the more complex
12 issue of how best to regulate commercial uses, as evidenced by its issuance of
13 the 2019 AMPRM upon the release of the 2019 Final Rule, and its Final Risk
14 Evaluation in 2020, in which it reached the very conclusion as to risk that
15 Environmental Petitioners contend it was required to reach in the 2019 Final
16 Rule: that commercial uses of methylene chloride in paint and coating
17 removal present an unreasonable risk of injury to health.

1 Notwithstanding the considerable force of Environmental Petitioners'
2 focus on the dangerousness of methylene chloride, we agree with EPA that its
3 consideration of commercial uses is prudentially unripe for judicial review at
4 this time. The record supports EPA's contention that judicial review at this
5 time would interfere in its consideration of the issue, would be no more likely
6 to advance than to hinder its arrival at a final determination, and, even
7 granting the relief Environmental Petitioners seek, would not necessarily
8 result in any reduction of harms from commercial use. Environmental
9 Petitioners have not shown that denial of the relief they now seek will subject
10 them to significant harms.

11 Under the doctrine of prudential ripeness, courts will decline to review
12 administrative action that would otherwise be reviewable under
13 constitutional and statutory standards because, upon a balancing of the
14 pertinent interests, it is preferable for judicial review to await a more
15 advanced state of administrative consideration. The standards for invocation
16 of the prudential ripeness doctrine are generally described as a two-prong
17 test. The first prong asks whether the issues are "fit" for judicial review,
18 which requires consideration of "whether the court or the agency would

1 benefit from postponing review until the policy in question has sufficiently
2 crystallized.” *Fla. Power & Light Co. v. EPA*, 145 F.3d 1414, 1421 (D.C. Cir.
3 1998) (internal quotation marks omitted). The second prong—the “hardship”
4 prong—asks “whether and to what extent the parties will endure hardship if
5 decision is withheld.” *NYCLU v. Grandeau*, 528 F.3d 122, 134 (2d Cir. 2008).
6 The court must consider whether “the interests of the court and the agency in
7 postponing review outweigh the interests of those seeking relief.” *Nat’l Ass’n
8 of Regul. Util. Comm’rs v. Dep’t of Energy*, 851 F.2d 1424, 1428 (D.C. Cir. 1988).
9 These broad articulations of judicial discretion are not clearly defined, but
10 what is clear is the need for balancing of competing interests.

11 Considerations that favor invocation of the doctrine to defer judicial
12 review include the desirability of (i) avoiding involving courts in “abstract
13 disagreements over administrative policies,” *Abbott Labs.*, 387 U.S. at 148; (ii)
14 preventing courts from exercising premature, unnecessary interference in
15 matters of governmental policy, *see NYCLU v. Grandeau*, 528 F.3d at 130-31;
16 and (iii) avoiding pernicious, unnecessary delay and obstruction of
17 administrative progress, particularly where the “possibility that further

1 consideration [by the agency] will actually occur . . . is not theoretical, but
2 real," *Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 735 (1998).

3 Considerations that weigh against deferring judicial review include
4 that (i) delaying judicial review can result in substantial harm to the interests
5 of those seeking review and (ii) judicial review can expedite successful
6 completion of the administrative task when an agency has embarked on a
7 route that does not comport with an obligatory legal framework.

8 Furthermore, the Supreme Court has recently noted "tension" between
9 exercise of prudential restraint and the Court's "recent reaffirmation of the
10 principle that a federal court's obligation to hear and decide cases within its
11 jurisdiction is virtually unflagging." *Lexmark Intern., Inc. v. Static Control*
12 *Components, Inc.*, 572 U.S. 118, 126 (2014) (internal quotation marks omitted).²

13 In general, the more the matter to be placed before the court involves a pure
14 issue of law, unaffected by factual considerations, the less the concern that
15 judicial review might interfere inappropriately with full, effective
16 administrative consideration or involve the court inappropriately in matters

² The Supreme Court has not "resolve[d] the continuing vitality of the prudential ripeness doctrine," *Susan B. Anthony List v. Driehaus*, 573 U.S. 149, 167 (2014).

1 of governmental policy. *See NYCLU v. Grandeau*, 528 F.3d at 132 (“[I]ssues
2 have been deemed [prudentially] ripe when they would not benefit from any
3 further factual development and when the court would be in no better
4 position to adjudicate the issues in the future than it is now.” (internal
5 quotations marks omitted)); *see also Gary D. Peake Excavating Inc. v. Town Bd. of*
6 *Hancock*, 93 F.3d 68, 72 (2d Cir. 1996) (finding ripe claims that were “purely
7 legal and may be decided without further factual development”).

8 We conclude that Environmental Petitioners’ challenge to the Final
9 Rule—on the ground that it should have also addressed and regulated
10 commercial uses—is prudentially unripe for review at this time. On the day
11 of its promulgation of the Final Rule, on March 27, 2019, EPA published an
12 ANPRM indicating its intent to proceed to the question of how to deal with
13 commercial uses. Then, one year and three months later, in June 2020, it
14 finalized a risk assessment determining that commercial uses posed an
15 unreasonable risk. By making that determination, the agency imposed on
16 itself a statutory deadline to finalize a § 2605(a) rule within two years, (subject
17 to the possibility of a two-year extension if certain conditions are met).
18 § 2605(c)(1). That record does not give substantial support to Environmental

1 Petitioners' argument that EPA's failure to include commercial uses in the
2 Final Rule was procrastination designed to postpone a resolution indefinitely.
3 Environmental Petitioners are undoubtedly correct that the agency's record
4 on this question since it first recognized the adverse health risks of methylene
5 chloride is unimpressive. Nonetheless, however disinclined the EPA may
6 have been in the past to deal with this difficult issue, its more recent record
7 does not support the conclusion that the agency's deferral of the commercial
8 question in 2019 was a device to stall resolution indefinitely. It rather
9 supports the conclusion that EPA now recognizes its obligations and is
10 pursuing them.

11 Environmental Petitioners lean heavily on the hardship prong of the
12 test of prudential ripeness, asserting that adverse health consequences will
13 result from continued access to methylene chloride in commercial use. We
14 cannot deny the possibility that delaying regulation of methylene chloride in
15 commercial uses might produce some harm. Indeed, if the delay occasioned
16 by our reliance on prudential ripeness were open-ended, Environmental
17 Petitioners would have a stronger argument against application of that
18 doctrine. The delay, however, is not open ended. In fact, given the steps EPA

1 has already taken, Environmental Petitioners have not successfully shown
2 that granting the relief sought would either bring about an earlier final
3 regulation or significantly reduce harms. Given that the deadline EPA has
4 taken on by finalizing the 2020 Final Risk Evaluation is rapidly approaching,
5 the harm resulting from EPA's postponement of the risk assessment for
6 commercial use until after dealing with consumer use is not enormous. Even
7 assuming that the risk of harm to commercial users might have been slightly
8 reduced had EPA determined that those uses pose an unreasonable health
9 risk and regulated them when it passed the Final Rule in 2019, it does not
10 necessarily follow that future harms would be reduced by now granting the
11 relief that petitioners seek. Granting that relief at this time could as easily
12 have the effect of delaying the ultimate resolution and increasing the harms,
13 rather than reducing them. Court-imposed pressure to reach a final scheme of
14 regulation before the agency has adequately collected and studied the needed
15 information could cause the agency to reach an inadequate solution that fails
16 to protect against harms as effectively as EPA might have protected if given
17 sufficient time. Moreover, even if we were to order EPA to revise the
18 challenged Final Rule to adopt regulations restricting commercial uses, EPA

1 would still need to consider a variety of regulatory options, the comparative
2 effectiveness of those options in ensuring that unreasonable risks are no
3 longer presented, and the reasonably ascertainable economic consequences of
4 those potential regulations. As a result, it is unlikely that EPA could comply
5 with our order before the expiration of the deadline EPA has already imposed
6 on itself by publishing the 2020 Final Risk Evaluation.

7 Nor do we think Environmental Petitioners are correct in arguing that
8 the issue before the court is a pure question of law, such as disfavors
9 application of the doctrine of prudential ripeness. While judicial review
10 inevitably raises questions of law, the questions whether commercial use of
11 methylene chloride presents an unreasonable risk of harm; if so, how that risk
12 of harm should be neutralized; and whether EPA's decision to delay
13 answering that question until after producing a final rule on consumer uses
14 was arbitrary, unreasonable, or not supported by substantial evidence are
15 very much dependent on factual considerations. It is not as if the issue in
16 dispute simply involved the interpretation of a statutory term or the
17 application of law to undisputed facts.

**United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007**

DEBRA ANN LIVINGSTON
CHIEF JUDGE

Date: September 01, 2021

Docket #: 19-1042ag

Short Title: Labor Council for Latin Americ v.

United States Environmental Pr

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Agency #: 84-11420

Agency: Environmental Protection Agency

Agency #: EPA-84FR11420

Agency: Environmental Protection Agency

BILL OF COSTS INSTRUCTIONS

The requirements for filing a bill of costs are set forth in FRAP 39. A form for filing a bill of costs is on the Court's website.

The bill of costs must:

- * be filed within 14 days after the entry of judgment;
- * be verified;
- * be served on all adversaries;
- * not include charges for postage, delivery, service, overtime and the filers edits;
- * identify the number of copies which comprise the printer's unit;
- * include the printer's bills, which must state the minimum charge per printer's unit for a page, a cover, foot lines by the line, and an index and table of cases by the page;
- * state only the number of necessary copies inserted in enclosed form;
- * state actual costs at rates not higher than those generally charged for printing services in New York, New York; excessive charges are subject to reduction;
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**United States Court of Appeals for the Second Circuit
Thurgood Marshall U.S. Courthouse
40 Foley Square
New York, NY 10007**

DEBRA ANN LIVINGSTON
CHIEF JUDGE

CATHERINE O'HAGAN WOLFE
CLERK OF COURT

Date: September 01, 2021

Agency #: 84-11420

Docket #: 19-1042ag

Agency: Environmental Protection Agency

Short Title: Labor Council for Latin Americ v.

Agency #: EPA-84FR11420

United States Environmental Pr

Agency: Environmental Protection Agency

VERIFIED ITEMIZED BILL OF COSTS

Counsel for

respectfully submits, pursuant to FRAP 39 (c) the within bill of costs and requests the Clerk to prepare an itemized statement of costs taxed against the

and in favor of

for insertion in the mandate.

Docketing Fee _____

Costs of printing appendix (necessary copies _____) _____

Costs of printing brief (necessary copies _____) _____

Costs of printing reply brief (necessary copies _____) _____

(VERIFICATION HERE)

Signature