UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

August Term, 2020

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

Docket Nos. 19-1042(L); 19-1044; 19-2329

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 MICHAEL S. REGAN,[*] as Administrator of the United States Environmental Protection Agency,

Respondents.

Before:

LEVAL, CABRANES, and RAGGI, *Circuit Judges*.

[*] 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.

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

JONATHAN KALMUSS-KATZ (Eve C. Gartner, *on the brief*), Earthjustice, New York, NY, *for Petitioner Labor Council for Latin American Advancement.*

THOMAS ZIMPLEMAN, NATURAL RESOURCES DEFENSE COUNCIL, WASHINGTON, DC, *for Petitioner Natural Resources Defense Council.*

ROBERT M. SUSSMAN, SUSSMAN & ASSOCIATES, WASHINGTON, DC, *for Petitioners Vermont Public Interest Research Group, Safer Chemicals Healthy Families, Lauren Atkins, and Wendy Hartley.*

W. CAFFEY NORMAN, Squire Patton Boggs (US) LLP, Washington, DC; KEITH BRADLEY (Alexander Arensberg, *on the brief*), Squire Patton Boggs (US) LLP, Denver, CO, *for Petitioner Halogenated Solvents Industry Alliance, Inc.*

DANIEL DEPASQUALE, BETHANY FISHER, Office of the General Counsel, United States Environmental Protection Agency, Washington, DC; JEFFREY BOSSERT CLARK, Assistant Attorney General; JONATHAN BRIGHTBILL, Principal Deputy Assistant Attorney General; SARAH A. BUCKLEY, Trial Attorney, United States Department of Justice, Washington, DC, *for Respondents*.

LEVAL, *Circuit Judge*:

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

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

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

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

BACKGROUND

I. Methylene Chloride and EPA's Evaluation of its Risks

TSCA imposes a duty on EPA to "conduct risk evaluations . . . 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." 15 U.S.C. § 2605(b)(4)(A). Under § 2605(a), if the Administrator of EPA determines that a chemical "presents an unreasonable risk of injury to health or the environment, the Administrator shall by rule . . . [impose] requirements to such substance . . . to the extent necessary so that [it] no longer presents such risk." In this opinion, we refer to rules promulgated

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

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

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

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

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

II. The 2017 Proposed Rule

In 2017, EPA proposed a § 2605(a) rule regarding commercial and consumer uses of methylene chloride in paint and coating removal. *See* 2017 Proposed Rule, 82 Fed. Reg. 7,464. The Proposed Rule was an exercise of the EPA's discretionary authority under 15 U.S.C. § 2625(*l*)(4), which permits promulgation of § 2605(a) rules for chemicals, such as methylene chloride, for which EPA had "published a completed risk assessment prior to June 22, 2016." 15 U.S.C. § 2625(*l*)(4). Relying on the 2014 Risk Assessment, EPA proposed to determine that both acute and chronic "methylene chloride exposures during paint and coating removal present unreasonable risks." 2017 Proposed Rule, 82 Fed. Reg. at 7,478. Accordingly, 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 prohibit the use of methylene chloride for commercial paint and coating removal in [several] specified sectors." *Id.* at 7,465. EPA did not propose to "regulate the use of

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

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

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

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

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

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

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

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

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

III. The Challenged Final Rule

On March 27, 2019, EPA promulgated the final rule at issue in this appeal. Methylene Chloride; Regulation of Paint and Coating Removal for Consumer Use Under TSCA Section 6(a), 84 Fed. Reg. 11,420 (Mar. 27, 2019) (hereafter "Final Rule"). The Final Rule set forth a determination by EPA 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," *id.* at 11,421 (emphasis added); on the other hand, it did not make a final determination—as it had proposed to do—that *commercial* uses posed an unreasonable risk. Instead, EPA published, on the same day, an Advanced Notice of Proposed Rule Making ("2019 ANPRM") "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." *Id.*; *see also* Methylene Chloride; Commercial Paint and Coating Removal Training, Certification and Limited Access Program, 84 Fed. Reg. 11,466 (Mar. 27, 2019) (hereafter "2019 ANPRM").

To ensure that consumer uses of products containing methylene chloride would "no longer present[]" the identified unreasonable risk in consumer products, the Final Rule prohibited the "manufacturing, processing and distributing in commerce methylene chloride for consumer paint and coating removal" and prohibited the distribution in commerce of methylene chloride (or products containing it) both to and by "retailers." 2019 Final Rule, 84 Fed. Reg. at 11,435. The Final Rule defined "retailer" 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. Any distributor with at least one consumer end user customer is a 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.

Id.

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

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

proposed in the 2019 ANPRM that a training and certification program, combined with limited access by commercial users, "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." 2019 ANPRM, 84 Fed. Reg. at 11,466. Though the 2017 Proposed Rule had already sought comments on such a program, EPA received only one responsive comment, from the Environmental Defense Fund, which was sharply critical. *Id.* at 11,468. But, as previously noted, in 2018, following the close of the comment period, HSIA submitted a white paper advocating for such a training and certification program. *Id.* EPA noted that such a program was similar to one used in the United Kingdom, where access to methylene chloride is restricted to certified commercial end users, while unobtainable by consumer end users. *Id.* at 11,469.

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

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

DISCUSSION

I. The Toxic Substances Control Act ("TSCA") and its Application to EPA's Evaluations and Regulations of Methylene Chloride

TSCA, originally enacted in 1976, was intended "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, and to give EPA "adequate authority . . . 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).

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

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

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

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

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

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

1 or more primary alternative regulatory actions considered by the
Administrator." § 2605(c)(2)(A)(iv). "[I]n deciding whether to prohibit or
restrict in a manner that substantially prevents a specific condition of use of a
chemical substance or mixture . . . [EPA] 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." § 2605(c)(2)(C). EPA's
duty to consider costs, as contemplated by these statutory provisions, is
subject to the overall mandate to regulate the chemical to the extent that it "no
longer presents" the identified unreasonable risk. § 2605(a).

Shortly prior to the 2016 amendment, EPA had completed risk
evaluations for several chemicals, including methylene chloride. TSCA's
amendment addressed such "chemical substance[s] . . . for which the
Administrator has published a completed risk assessment prior to June 22,
2016." § 2625(*l*)(4). Rather than requiring EPA to re-complete risk assessments
for these chemicals, the 2016 amendment provides that "the 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 and consistent with other applicable requirements of section 2605 of this title." *Id.*

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

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

II. Standard of Review

For judicial review of rules promulgated by EPA under § 2605(a), TSCA provides a standard worded slightly differently from the standard established by § 706 of the Administrative Procedure Act ("APA"). The APA's standard of review provides that reviewing courts shall set aside agency action that is "unsupported by substantial evidence." 5 U.S.C. § 706(2)(E). "Substantial evidence" under the APA has been understood to mean "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 that standard, a court will not set aside an agency's action so long as it is "supported by less than a preponderance but more than a scintilla of evidence." *Sprint Spectrum L.P. v. Willoth*, 176 F.3d 630, 638 (2d Cir. 1999) (internal quotation marks omitted). "Substantial evidence [under the APA] requires 'something less than the weight of the evidence, and the possibility of drawing two inconsistent conclusions from the evidence does not prevent an administrative agency's finding from being supported by substantial evidence.'" *Corrosion Proof*, 947 F.2d at 1213 (quoting *Consolo v. Federal Maritime Comm'n*, 383 U.S. 607, 620 (1966)).

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

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

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

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

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[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)).

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

III. HSIA's Challenge to the 2019 Final Rule

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

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

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

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

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

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

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

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

HSIA contends that EPA provided insufficient notice and opportunity to comment on the definition of "retailer" in the final rule. EPA was required to 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 5 U.S.C. § 553 applies to § 2605(a) rules). "Courts of Appeals 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) (internal quotation marks omitted); *see also Nat'l Black Media Coal v. FCC*, 791 F.2d 1016, 1022 (2d Cir. 1986). Accordingly, "a final rule need not be an exact replica of the rule proposed in the Notice," *Nat'l Black Media*, 791 F.2d at 1022, and the standard is generally satisfied if the notice given by the agency fairly apprises interested persons of the subjects and issues that will be resolved by the adoption of a final rule. *See Riverkeeper, Inc. v. EPA*, 475 F.3d 83, 113 (2d Cir. 2007), *rev'd on other grounds sub nom. Entergy Corp. v. Riverkeeper, Inc.*, 556 U.S. 208 (2009). We have explained that "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. v. EPA*, 905 F.3d 49, 71 (2d Cir. 2018) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm*, 463 U.S. 29, 43 (1983)). TSCA additionally requires EPA to "publish a notice of proposed rulemaking stating with particularity the reason for the proposed rule." 15 U.S.C. § 2605(c)(3)(A).

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

We reject HSIA's argument. We find that EPA satisfied the "logical outgrowth" standard as we have interpreted it and complied with TSCA's

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

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

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

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

action until submitted commentary and further study failed to suggest any desirable modification. Such an interpretation of the notice and comment requirement would seriously harm the ability of agencies to deal flexibly with pressing problems. More importantly, such an interpretation would be plainly inconsistent with the statutory standard requiring that the "notice of proposed rulemaking . . . include . . . 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).

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

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

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

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

estimate was extrapolated from a survey addressing the manufacturing marketspace for similar products in Canada, and an additional survey regarding another chemical, trichloroethylene (also known as "TCE"), which EPA used to confirm the applicability for a U.S. rulemaking of the first survey's study of a Canadian market. And EPA found 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." 2019 Final Rule, 84 Fed. Reg. at 11,427-28.

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

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

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

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

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

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

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

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

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

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

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

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

* * *

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

IV. Environmental Petitioners' Challenge to the 2019 Final Rule

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

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

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

several arguments that there should be no judicial review of its deliberations on commercial uses until it reaches final determinations. Among those arguments, it asserts that its consideration of commercial uses is prudentially unripe for judicial review, as judicial review at this time would involve "judicial interference [before] 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), without substantial alleviation of hardship to the petitioners. EPA points out that it has not procrastinated, nor ignored the significant risks arising from commercial uses of methylene chloride. It rather opted to begin with the easier task of developing a regulatory scheme for consumer uses and then turning to the more complex issue of how best to regulate commercial uses, as evidenced by its issuance of the 2019 AMPRM upon the release of the 2019 Final Rule, and its Final Risk Evaluation in 2020, in which it reached the very conclusion as to risk that Environmental Petitioners contend it was required to reach in the 2019 Final Rule: that commercial uses of methylene chloride in paint and coating removal present an unreasonable risk of injury to health.

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

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

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

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

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

Considerations that weigh against deferring judicial review include that (i) delaying judicial review can result in substantial harm to the interests of those seeking review and (ii) judicial review can expedite successful completion of the administrative task when an agency has embarked on a route that does not comport with an obligatory legal framework. Furthermore, the Supreme Court has recently noted "tension" between exercise of prudential restraint and the Court's "recent reaffirmation of the principle that a federal court's obligation to hear and decide cases within its jurisdiction is virtually unflagging." *Lexmark Intern., Inc. v. Static Control Components, Inc.*, 572 U.S. 118, 126 (2014) (internal quotation marks omitted).[2] In general, the more the matter to be placed before the court involves a pure issue of law, unaffected by factual considerations, the less the concern that judicial review might interfere inappropriately with full, effective 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).

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

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

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

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

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

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

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

The deadline for a final risk management rule regarding commercial uses of methylene chloride is rapidly approaching. We conclude that the extent to which TSCA requires EPA to regulate commercial uses of methylene chloride, and whether the rules EPA promulgates adequately do so, will be a better fit for judicial review after that rulemaking process is complete and the "policy in question has sufficiently crystallized." *Fla. Power & Light*, 145 F.3d at 1421 (internal quotation marks omitted). Judicial review at this time, in the absence of a record that fully considered regulation of commercial uses, might force the court to cope with abstract disagreements and involve itself in matters of administrative policy without the benefit of illuminating information. *See Abbott Labs.*, 387 U.S. at 148-49 (1967).

Accordingly, we hold that Environmental Petitioners' challenges to the 2019 Final Rule are prudentially unripe for review at this time. Their petitions for review are DENIED.

CONCLUSION

For the foregoing reasons, the petitions for review of the 2019 Final Rule are DENIED.