18-25

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL,
Petitioner,

SAFER CHEMICALS HEALTHY FAMILIES,
Intervenor-Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
Respondent,

AMERICAN CHEMISTRY COUNCIL, NATIONAL ASSOCIATION OF MANUFACTURERS,
Intervenor-Respondents.

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

OPENING BRIEF OF PETITIONER NATURAL RESOURCES DEFENSE COUNCIL

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CORPORATE DISCLOSURE STATEMENT

Petitioner Natural Resources Defense Council, Inc. (NRDC), is a non-profit organization with no parent corporations and no outstanding stock shares or other securities in the hands of the public. NRDC does not have any parent, subsidiary, or affiliate that has issued stock shares or other securities to the public. No publicly held corporation owns any stock in NRDC.

Dated: May 1, 2018

/s/ *Thomas Zimpleman*
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INTRODUCTION

Toxic chemicals pervade our environment. Through 2016 amendments to the Toxic Substances Control Act (TSCA), Congress created a robust set of protections to shield the public from the health and environmental effects of these chemicals, especially for individuals who are most vulnerable to harm from chemical exposures. The Environmental Protection Agency (the Agency or EPA) is eroding those safeguards for its own administrative convenience, and for the benefit of chemical manufacturers. This effort is illegal and warrants the Court's intervention.

The Administrative Procedure Act (APA) bars an agency from taking action that contravenes express instructions from Congress. The APA also requires an agency to follow specified procedures when it issues rules with legal effect. EPA ran afoul of both principles when it promulgated, without public notice and comment, a final rule that unlawfully truncates EPA's review of manufacturers' notices of new chemicals or new chemical uses.

When a manufacturer proposes to introduce a new chemical to the market, it must file a premanufacture notice with EPA, triggering the Agency's obligation to review the health and environmental effects of

the new chemical. In 2016, Congress strengthened this premanufacture review program through the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016) (Lautenberg Chemical Safety Act). Under the Act, EPA may allow the unrestricted manufacture of a new chemical substance *only* when it affirmatively finds that the substance "is not likely to present an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use." 15 U.S.C. § 2604(a)(3)(C). The "conditions of use" under which EPA is required to review premanufacture notices are defined as "the circumstances, as determined by the Administrator, under which a chemical substance is *intended, known, or reasonably foreseen* to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4) (emphasis added). If EPA *cannot* determine that the chemical substance is unlikely to present an unreasonable risk of injury to health or the environment under its conditions of use, it must issue an order restricting the manufacture, importation, processing, or distribution in commerce of that chemical to

the extent necessary to protect against an unreasonable risk. *Id.* § 2604(e), (f).

Initially, EPA faithfully implemented the amendments to the section 5 process ushered in by the Lautenberg Chemical Safety Act. After a change in administration, however, the Agency reversed course and promulgated a final rule, which EPA characterized as its "Decision-making Framework" (Framework Rule). In the Framework Rule, EPA announced that it will issue determinations that a chemical is "not likely to present an unreasonable risk" based only on the *intended* conditions of use, as presented in the manufacturer's notice, even if there are other known or reasonably foreseen uses that create risks. If EPA has risk concerns for known or reasonably foreseen conditions of use, EPA intends to address those concerns through significant new use rules. However, significant new use rules are notification provisions that lack the same protective measures as consent orders, and Congress did not intend for EPA to use them in these circumstances. The Agency promulgated the rule in defiance of Congress's requirement that EPA evaluate each new chemical substance under the conditions of use that are intended, *known*, or *reasonably foreseen*, and that the Agency issue binding orders when it is unable to make a finding of no risk. EPA also

failed to provide public notice or an opportunity to comment on the rule before it was adopted. The Framework Rule is thus illegal on its face, was promulgated without proper procedure, and should be vacated.

STATEMENT OF JURISDICTION

Petitioner Natural Resources Defense Council (NRDC) challenges the Framework Rule that governs EPA's review of new chemical substances under section 5 of TSCA. This Court has jurisdiction to review final rules issued by EPA under TSCA. *See* 15 U.S.C. § 2618(a)(1)(A); *see also Cent. & S. W. Servs., Inc. v. EPA*, 220 F.3d 683, 687 (5th Cir. 2000).

As explained in greater detail below (see *infra* Part I.A), venue is proper in this Court because petitioner NRDC resides in this Circuit, 15 U.S.C. § 2618(a)(1)(A); Add. 49, Trujillo Decl. ¶ 3. The petition for review is timely because it was filed on January 5, 2018, JA__, which is "not later than 60 days after the date on which a rule is promulgated." 15 U.S.C. § 2618(a)(1)(A).

NRDC also has standing to challenge the Framework Rule for the reasons explained below (see *infra* Part III).

STATEMENT OF THE ISSUES PRESENTED

1. Is the Framework Rule contrary to the plain statutory language of section 5 of TSCA?

2. Did the Agency violate the APA by failing to provide notice and an opportunity to comment before promulgating the Framework Rule?

STATEMENT OF THE CASE

NRDC asks this Court to review and set aside the Framework Rule promulgated by EPA. The Framework Rule was announced on November 7, 2017, and published on EPA's website. *See* New Chemicals Decision-Making Framework, JA __.[1] This rule illegally narrows the risk assessments that EPA conducts for premanufacture notices and eliminates environmental and health protections that Congress required EPA to put in place when a new chemical substance presents risk concerns under its intended, known, or reasonably foreseen conditions of use.

[1] https://www.epa.gov/sites/production/files/2017-11/documents/new_chemicals_decision_framework_7_november_2017.pdf (last visited May 1, 2018). This document is listed in the Supplemental Index filed by EPA. *See* Supp. Index, ECF No. 56-2, at 4.

Section 5 of TSCA Governs Reviews of New Chemicals for Health and Environmental Risks

In 1976, Congress enacted the Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (1976), finding that "human beings and the environment are being exposed each year to a large number of chemical substances and mixtures," 15 U.S.C. § 2601(a)(1), and that, "among the many chemical substances and mixtures which are constantly being developed and produced, there are some whose manufacture, processing, distribution in commerce, use, or disposal may present an unreasonable risk of injury to health or the environment," *id.* § 2601(a)(2).

Section 5 of TSCA, as amended, governs EPA's review of "new chemical substance[s]," defined as chemical substances that are not included on a TSCA-mandated inventory of approved chemical substances. *See* 15 U.S.C. §§ 2604(a)(1)(A), 2602(11); *see also id.* § 2607(b)(1) ("[EPA] shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States."). Generally, no person may manufacture (a term that is defined to include import, *id.* § 2602(9)) a "new chemical substance" in the United States without providing EPA with a premanufacture notice

at least 90 days before manufacturing the substance, *id.* § 2604(a)(1)(A), (B)(i).

The submitter must include, "insofar as known to the person submitting the notice or insofar as reasonably ascertainable," information identified in section 8(a)(2) of TSCA. *See id.* §§ 2604(d)(1)(A), 2607(a)(2)(A)-(D), (F), (G). This information includes the substance's chemical identity, the proposed new uses of the chemical, reasonable estimates of the total amount to be manufactured or processed, a description of byproducts, reasonable estimates of the number of individuals who will be exposed, and the manner or method of disposal of the chemical. *See id.* § 2607(a)(2)(A)-(D), (F), (G). In addition, the submitter must include "any information in the possession or control of the person giving such notice which are [sic] related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment." *Id.* § 2604(d)(1)(B). Finally, the premanufacture notice must also include "a description of any other information concerning the environmental and health effects of such substance, insofar as known to

the person making the notice or insofar as reasonably ascertainable." *Id.* § 2604(d)(1)(C).

As originally enacted, section 5 of TSCA did not require EPA to make any determination regarding the safety of a new chemical substance. *See* § 5, 90 Stat. 2012. Instead, the statute required a manufacturer to give EPA notice of its intent to begin using a new chemical substance; EPA was given time to review the notice, *id.* § 5(a), 90 Stat. 2012-13, and if the Agency had concerns about the health or environmental risks of the substance, it was authorized (but not required) to take various preventive measures, *id.* § 5(e)-(f), 90 Stat. 2015-18. On the expiration of the applicable review period, absent action by EPA, the manufacturer could commence using a new chemical substance in commercial applications. *Id.* § 5(a)(1), 90 Stat. 2012.

Congress Directs EPA to Make an Affirmative Determination on the Health and Environmental Risks of New Chemical Substances

In the 2016 amendments, Congress made "significant changes to [EPA's] passive approach under current law," 162 Cong. Rec. S3511, S3516 (daily ed. June 7, 2016) (statement of Sen. Merkley). For the first time, Congress required EPA "to review all new chemicals and significant new uses and make an affirmative finding regarding the

chemical's or significant new use's potential risks." *Id.* Congress amended section 5 to bar the manufacture of a chemical "in the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk." *Id.*; *see* 15 U.S.C. § 2604(a)(1), (3).

The required determinations. EPA must make one of five determinations regarding the environmental and health risks of a new chemical substance:

(1) the chemical "presents an unreasonable risk of injury to health or the environment," 15 U.S.C. § 2604(a)(3)(A);

(2) the available information "is insufficient to permit a reasoned evaluation of the health and environmental effects" of the chemical, *id.* § 2604(a)(3)(B)(i);

(3) in the absence of sufficient information, the "manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment," *id.* § 2604(a)(3)(B)(ii)(I);

(4) the substance "is or will be produced in substantial quantities" and either will or may "enter the environment in substantial

quantities" or will or may result in "significant or substantial human exposure," *id.* § 2604(a)(3)(B)(ii)(II); or

(5) the substance "is not likely to present an unreasonable risk of injury to health or the environment," *id.* § 2604(a)(3)(C).

What EPA must review when making these determinations. When considering premanufacture notice and making these determinations, EPA must review the "conditions of use" of the substance; 15 U.S.C. § 2604(a)(3)(A), (C), defined as "the circumstances, as determined by [EPA], under which a chemical substance is *intended, known, or reasonably foreseen* to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4) (emphasis added). Congress's decision in 2016 to require EPA to evaluate a chemical substance's conditions of use—whether intended, known, or reasonably foreseen—was significant; the original version of TSCA did not contain a provision defining "conditions of use" or requiring EPA to evaluate them. *See* § 3, 90 Stat. 2004-05.

The 2016 amendments' emphasis on "conditions of use" reflects the reality that chemicals are often used in commercial applications different from those intended by the manufacturer. This occurs in several ways. First, companies use chemical substances in various

products, and the chemical's manufacturer is not necessarily aware of all of these products. Under the original TSCA, "the chemical manufacturers have had essentially no knowledge of how their chemicals have actually been used in the market. Chemicals intended for degreasing, for example, have appeared in all kinds of applications, from aerosol spray cans to hand-operated pumps, to brushable solutions, to degreasing baths." *Cmts. of the Blue-Green Alliance* 1 (Dec. 19, 2016), EPA-R-008, JA __.

Second, chemicals can be produced by different manufacturers using different methods, causing important differences in the health effects of the resulting chemical. EPA's presentations at its December 14, 2016, public meeting provided one example. A chemical substance has a reactive component, which has been shown to cause a variety of adverse effects, from either respiratory or skin exposure, and from exposure at very low doses. However, the new chemical substance is manufactured in such a way that there is no "free" reactive component in the chemical substance to create exposure. But once the new chemical substance is placed on the TSCA inventory, the chemical substance *can* be manufactured in a way in which there will be free reactive components. Manufacture, processing, and use associated with

these uses will result in worker and consumer exposure. This use is "foreseen," given the information on chemicals with this reactive component, and thus EPA needs to consider the health and environmental effects of the reactive component. *Reviewing New Chemicals Under the Toxic Substances Control Act* 31-32 (Dec. 14, 2016), EPA-R-002, JA __; *see also Cmts. of Safer Chemicals Healthy Families, et al., on Improvements to the New Chemicals Review Program under the Amended Toxic Substances Control Act* 11-12 (Jan. 17, 2017), EPA-HQ-OPPT-2016-0658-0033, JA __ (discussing this example).

Third, reasonably foreseen conditions of use are not limited to differences in manufacturing. They also include, for example, reasonably foreseeable workplace exposures, and downstream exposures from the disposal of the chemical or products containing the chemical. *Cf.* 15 U.S.C. § 2602(4) (defining "conditions of use" to include reasonably foreseen conditions in which a chemical is used or disposed of). "[W]orkers are exposed to chemicals in settings and during applications which are beyond those listed by a manufacturer in its pre-manufacture notice to EPA. These settings and applications may occur during production, processing, distribution, use and/or disposal of a chemical." *Cmts. of the Am. Pub. Health Ass'n* 1 (Jan. 17, 2017), EPA-

HQ-OPPT-2016-0658-0032, JA __. Food sources that absorb environmental contamination are additional exposure pathways that may be captured only by considering reasonably foreseen conditions of use. *Cmts. of the Nat'l Tribal Toxics Council* 2 (Jan. 17, 2017), EPA-R-010, JA __.

The statutory consequences for each of the five determinations. If EPA determines that a new chemical substance subject to a premanufacture notice "presents an unreasonable risk of injury to health or environment," then EPA "shall, before the expiration of the applicable review period," take one of two actions. 15 U.S.C. § 2604(f)(1). EPA can "issue a proposed rule" restricting, prohibiting, or otherwise regulating the commercial use of the new chemical, and that proposed rule "shall be effective upon its publication in the Federal Register." *Id.* § 2604(f)(2). Or EPA can "issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made," and that order "shall take effect on the expiration of the applicable review period." *Id.* § 2604(f)(3)(A).

Similarly, EPA "shall" issue an order under section 5 whenever "the information available to [EPA] is insufficient to permit a reasoned

evaluation of the health and environmental effects of a chemical substance." *Id.* § 2604(e)(1)(A)(i). The order must prohibit or limit manufacturing or other commercial activities "to the extent necessary to protect against an unreasonable risk." *Id.* § 2604(e)(1)(A). Notably, EPA may by order also require the manufacturer to conduct additional tests on the safety risks of a particular chemical substance where there is otherwise insufficient information. *Id.* § 2603(a)(1), (2). The 2016 amendments provided EPA with authority to close these informational gaps. *See* 162 Cong. Rec. S3511, S3516 (daily ed. June 7, 2016) (statement of Sen. Merkley) ("EPA can also require additional testing."). As amended, section 5 provides more vigorous protection: Under the original version of TSCA, if EPA lacked sufficient information to make a risk finding, it "may" issue an order regulating the new chemical, but was not required to do so. *See* § 5(e), 90 Stat. at 2015.

The 2016 amendments also introduced a new provision—section 5(f)(4), codified at 15 U.S.C. § 2604(f)(4)—that requires EPA to follow up any order issued under section 5(e) or 5(f) of TSCA with either a proposed significant new use rule to govern any non-conforming uses of a new chemical substance covered by a section 5 order, or to publish a statement in the Federal Register explaining why it has declined to

propose such a rule. 15 U.S.C. § 2604(f)(4). EPA has 90 days from the date it issues an order under section 5 to propose a new use rule or publish an explanation why it is not doing so. *Id.*

TSCA permits the immediate manufacture, importation, or processing of a new chemical substance only if EPA makes determination (5): "that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment . . . including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use." *Id.* § 2604(a)(3)(C).

The combined changes to section 5—the requirement that EPA make an affirmative determination about a new chemical's safety, the mandatory issuance of orders to address environmental and health concerns, and the ability to require additional testing in the absence of sufficient information—were necessary and appropriate. These amendments were, as one leading proponent of the legislation put it, "essential to restoring the public's confidence in our chemical safety system." 162 Cong. Rec. S3511, S3516 (daily ed. June 7, 2016) (statement of Sen. Merkley).

EPA Initially Begins to Faithfully Implement the Amended Section 5 Process

Immediately after the passage of the 2016 amendments, EPA began to develop a review process that adhered to TSCA's requirements. EPA's public outreach included opening a "non-rulemaking" docket on Regulations.gov and holding a public meeting to accept public comment on the implementation of the amendments to section 5.[2] As the Agency explained at its December 2016 public meeting, it would not permit a new chemical substance to enter commercial use without making an affirmative determination as to its safety and health risks. *See Reviewing New Chemicals Under the Toxic Substances Control Act* 13, 19 (Dec. 14, 2016), EPA-R-002, JA __; *Reviewing New Chemicals Under the Toxic Substances Control Act—Science Issues* 8 (Dec. 14, 2016), EPA-R-003, JA __. EPA based these risk determinations on the full scope of the new chemical substances' conditions of use—intended, known, and reasonably foreseen. *Reviewing New Chemicals Under the Toxic Substances Control Act—Science Issues* 8 (Dec. 14, 2016), EPA-R-003, JA __.

[2] The docket is available at: https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2016-0658.

Regulated industries did not receive these developments warmly. *See TSCA Stakeholder Meeting—New Chemicals Program Transcript of Public Comments—December 14, 2016*, at 7, 11-12, 25-26, 31 (undated), EPA-R-013, JA __. With respect to TSCA's requirements that a manufacturer submit sufficient information to EPA to permit a full evaluation of the environmental and health risks of its products, industry advocates complained that EPA's review was creating a "backlog" of premanufacture notices. *Id.* at 4 (comment of American Chemistry Council). And industry representatives urged EPA to abandon the full review of all conditions of use for a new chemical substance reasonably foreseeable by EPA, and instead, to limit the review to information supplied by the manufacturer about the chemical's use. *Id.* at 5.

Soon thereafter, when the administration changed, EPA reversed course. In August 2017, EPA Administrator Scott Pruitt issued a press release in which he announced that he was "committing the Agency" to various operating principles for making safety determinations. *EPA Eliminates New-Chemical Backlog, Announces Improvements to New*

Chemical Safety Reviews (Aug. 7, 2017).[3] Among the "operating principles" to which EPA "committ[ed]" itself was the following: "Where the intended uses in premanufacture notices (PMNs) . . . raise risk concerns, EPA will work with submitters, and, if the submitters submit timely amended PMNs addressing those concerns, EPA will generally make determinations based on those amended submissions." *Id.* Additionally, Administrator Pruitt announced that under these new operating principles, "[w]here EPA has concerns with reasonably foreseen uses, but not with the intended uses as described in a PMN . . . , as a general matter, those concerns can be addressed through significant new use rules." *Id.*

Three months after Administrator Pruitt's press release, EPA's Office of Pollution Prevention and Toxics (Toxics Office) published the Framework Rule challenged here. *See* New Chemicals Decision-Making Framework (Nov. 2017), JA __. The Framework Rule "outlines EPA's approach to making decisions on new chemical notices submitted to EPA under TSCA section 5," and presents "EPA's general decision

[3] This document is listed in the Supplemental Index filed by EPA, *see* Supp. Index, ECF No. 56-2, at 4 (Apr. 5, 2018), and is available at https://www.epa.gov/newsreleases/epa-eliminates-new-chemical-backlog-announces-improvements-new-chemical-safety-reviews.

framework for new chemicals." *Id.* at 1. As part of the "[o]verall framework," *id.*, EPA reiterated two of the principles stated by Mr. Pruitt in his press release. "Where the conditions of use identified in submissions raise risk concerns, if the submitters provide timely written amendments to their submissions addressing those concerns, in general EPA will consider the conditions of use in those amended submissions to be the intended conditions of use." *Id.* at 2. And, once again:

> Where EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use as described in a submission (original or amended), EPA will assess whether those concerns can be addressed through significant new use rules (SNURs). The expectation is that SNURs will generally be effective vehicles to address such concerns and that, as a general matter, EPA will address such concerns through SNURs.

Id. The statute, however, provides for significant new use rules as a *follow-up* to enforceable orders or regulation under section 5(e) or section 5(f), not as a substitute. *See* 15 U.S.C. § 2604(f)(4). Significant new use rules are merely notification requirements not enforceable restrictions on manufacturing, processing, distribution, or disposal of potentially harmful chemicals.

As EPA has explained, under the Framework Rule it intends to use significant new use rules "to address *reasonably foreseen conditions*

of use about which EPA has *concerns*, as part of the basis for EPA to conclude that the chemical is *not likely to present an unreasonable risk* of injury to health and the environment under the conditions of use under section 5(a)(3)(C)." *Actions Under TSCA Section 5: SNURs for New Chemicals*, (emphases added).[4] Thus, despite its "concerns" about the reasonably foreseen conditions under which a new substance will be used, EPA will nevertheless find that the chemical is "not likely to present an unreasonable risk" to health or the environment based on a significant new use rule. EPA is using this approach, which Petitioner will describe hereafter as the "no-order policy," to narrow the scope of review of a premanufacture notice—that is, "to focus its technical analysis on the intended conditions of use of a chemical and *defer*

[4] This document is available on EPA's website: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs. The Court can take judicial notice of this document under Federal Rule of Evidence 201. *See Wells Fargo Bank, N.A. v. Wrights Mill Holdings, LLC*, 127 F. Supp. 3d 156, 166 (S.D.N.Y. 2015) ("Courts routinely take judicial notice of . . . governmental records" that have been "retrieved from official government websites.") (collecting cases). Further, it is appropriate for the Court to consider post-promulgation evidence of how EPA is applying the Framework Rule in order to resolve questions of finality. *See Gen. Elec. Co. v. EPA*, 290 F.3d 377, 383 (D.C. Cir. 2002) ("an agency pronouncement will be considered binding as a practical matter if it either appears on its face to be binding, *or is applied by the agency in a way that indicates it is binding*." (emphasis added)).

further analysis of reasonably foreseen conditions of use until such time as the submitter (or any other entity) actually intends to undertake them." *Id.* (emphasis added).

EPA opened an after-the-fact "non-rulemaking" docket on Regulations.gov through which the public could submit comments to EPA on the Framework Rule.[5] This docket is not part of a formal rulemaking record, and EPA has not committed to responding to public comments on the Framework Rule. Among other relevant documents, this docket contains a transcript of an EPA public meeting held on December 6, 2017, to discuss the Framework Rule.

At that meeting, Dr. Jeff Morris, the director of EPA's Toxics Office, characterized the Framework Rule as "governing" the decisions of the Toxics Office when reviewing premanufacture notices, and stated that the Toxics Office was "acting on the framework." Transcript December 6, 2017, New Chemicals Public Meeting with EPA Presentations at 10 ("As a framework for making our decisions, we need to make decisions because the 100 submissions per month keep coming, so we are doing that and we are acting on the framework and governing

[5] This docket is available at: https://www.regulations.gov/docket?D=EPA-HQ-OPPT-2017-0585.

ourselves by the framework.").[6] Further, Mr. Morris acknowledged that EPA was identifying cases in which it would address risk concerns raised by reasonably foreseen conditions of use through the promulgation of a significant new use rule rather than an enforceable consent order under sections 5(e) or 5(f) of TSCA. *See id.* at 51 ("[A]s part of acting on the framework, we are looking at those cases now that we think could be amenable to those. In other words, ones where we have concerns only with the reasonably foreseen uses and working them through our decision process to determine whether they are amenable to a SNUR. . . we are actively working to move this aspect of the framework forward."); *see also id.* at 21 ("Any time you establish a new decision framework, you want to be sure from the top of the office on down that *we are executing on the framework consistently*. . . . So, it is true. For the time being, I have asked that all determinations come up to me for the group's recommendation on how they *are consistent with the framework*." (emphasis added)).

Petitioner NRDC and Intervenor-Petitioner Safer Chemicals Healthy Families wrote to EPA on December 11, 2017, and requested

[6] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0076 (last visited Apr. 30, 2018).

that EPA "halt implementation of the framework while it reviews and addresses public comments and reexamines the framework's legality." Letter from Safer Chemicals Healthy Families, et al. to Dr. Jeff Morris 1 (Dec. 11, 2017), JA __.[7] EPA has not responded to that letter. NRDC filed its petition for review with the Court on January 5, 2018. *See* Petition for Review, JA __.

SUMMARY OF THE ARGUMENT

The Framework Rule violates two basic principles of administrative law, each of which provides independent grounds for vacating it.

1. The Framework Rule is contrary to law because its no-order policy contradicts the express requirements of section 5 of TSCA. EPA must review a new chemical substance under its "conditions of use," which are defined as the circumstances in which the substance "is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." 15 U.S.C. § 2602(4). If EPA has concerns about a chemical's effects on health or the environment, it must issue an order to restrict manufacture, processing,

[7] https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0032 (last visited Apr. 30, 2018).

or distribution under section 5(e) or 5(f) of TSCA. See *id.* § 2604(e), (f). The Framework Rule, however, permits EPA to determine that a chemical is "not likely to present an unreasonable risk" based on a review only of its *intended* conditions of use (and even there, based only on the intended conditions of use in the most recently amended premanufacture notice). Under the Framework Rule, if EPA has concerns about a chemical's effects on health or the environment under its known or reasonably foreseen conditions of use, the Agency will not issue an order to restrict the chemical. Instead, EPA will (eventually) promulgate a significant new use rule. This scheme is not permissible under TSCA. Congress "has directly spoken to the precise question at issue" in the text of TSCA; the Agency "shall" issue an order restricting the chemical under section 5(e) or 5(f) when it has risk concerns, and EPA is not free to adopt a more lax set of requirements. *Chevron, U.S.A., Inc. v. NRDC*, 467 U.S. 837, 842-43 (1984).

2. EPA violated the APA by failing to provide notice and an opportunity to comment on the Framework Rule. "Section 4 of the APA, 5 U.S.C. § 553, specifies that an agency shall afford interested persons general notice of proposed rulemaking and an opportunity to comment *before* a substantive rule is promulgated." *Chrysler Corp. v. Brown*, 441

U.S. 281, 313 (1979) (emphasis added). The Framework Rule is a substantive rule that directs the scope of EPA's review of premanufacture notices and the circumstances under which the Agency will take regulatory actions based on that review. It was published on EPA's website on November 7, 2017, with no prior notice or opportunity for public comment. The fact that EPA afforded interested parties an opportunity to comment *after* the Framework Rule was published is of no significance. EPA has admitted that the Framework Rule went into immediate use, and post-promulgation notice and comment does not cure the agency's procedural violation. *See NRDC v. Abraham*, 355 F.3d 179, 206 & n.14 (2d Cir. 2004).

STANDARD OF REVIEW

TSCA adopts the standard of review found in section 706 of the APA. *See* 15 U.S.C. § 2618(c)(1)(B); *see also Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1036 (D.C. Cir. 2012). The Court must therefore "hold unlawful and set aside" the Framework Rule if it is either (1) "in excess of statutory . . . authority," (2) "without observance of procedure required by law," or (3) "arbitrary" and "capricious." 5 U.S.C. § 706(2)(A), (C), (D).

ARGUMENT

I. The Court has authority to vacate the Framework Rule

A. The petition is timely and venue is proper

NRDC's petition for review is timely, and venue is proper. TSCA permits a party to file a petition for review in the Circuit Court in which it resides or has its principal place of business. 15 U.S.C. § 2618(a)(1)(A). Venue is proper in this Court because petitioner NRDC resides in New York. Trujillo Decl. ¶ 3. The petition for review is timely because it was filed less than 60 days after the Framework Rule was promulgated. 15 U.S.C. § 2618(a)(1)(A).

B. The Framework Rule is final and reviewable

The issues presented by this petition are ripe for adjudication now. Whether administrative action is ready for judicial review depends upon (1) the fitness of the issues for judicial decision, and (2) in cases where pre-enforcement review is not expressly permitted, the hardship to the parties of withholding court consideration. *Abbott Labs. v. Gardner*, 387 U.S. 136, 149 (1967). Whether the Framework Rule is contrary to TSCA is a question of law that does not require extensive factual development. *See Atl. States Legal Found., Inc. v. EPA*, 325 F.3d 281, 284 (D.C. Cir. 2003) ("Claims that an agency's action is arbitrary

and capricious or contrary to law present purely legal issues."); *see also Baraket v. Holder*, 632 F.3d 56, 58 (2d Cir. 2011) ("how to properly interpret" a statute "presents solely a question of law"). Similarly, whether EPA erred by adopting the Framework Rule without notice and comment is a legal question. *See Gen. Elec. Co.*, 290 F.3d at 380. The issues presented by NRDC's petition are thus fit for judicial decision.

The Framework Rule is also final agency action suitable for judicial review under the APA. The Framework Rule marks the consummation of EPA's decisionmaking process, and it determines the rights and obligations of EPA and manufacturers. *See Bennett v. Spear*, 520 U.S. 154, 178 (1997). It makes no difference that EPA has described the Framework Rule as a "working approach" that it "expects to evolve" as it "continues to gain experience with new chemicals decision making under amended TSCA." New Chemicals Decision-Making Framwork at 1; *see also* 82 Fed. Reg. 51,415 (Nov. 6, 2017), EPA-R-021, JA__ ("The Agency plans to utilize the feedback it receives from the public meeting and comments received to improve the policy and processes relating to the review of new chemicals under TSCA."). EPA is applying the Framework Rule now, *see supra* pp. 20-21, and thus it is final for

purposes of judicial review, notwithstanding any unspecified future revisions. *See Gen. Elec. Co.*, 290 F.3d at 380 ("If the possibility (indeed, the probability) of future revision in fact could make agency action non-final as a matter of law, then it would be hard to imagine when any agency rule—and particularly one that must be updated periodically to reflect advances in science—would ever be final as a matter of law."); *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1022 (D.C. Cir. 2000) ("The fact that a law may be altered in the future has nothing to do with whether it is subject to judicial review at the moment.").

There is no need for the Court to consider whether to defer judicial review under the second prong of the *Abbott Labs* test, which concerns the hardship to the parties of withholding review. TSCA requires a party to petition for pre-enforcement judicial review by filing within 60 days of a rule's promulgation. *See* 15 U.S.C. § 2618(a)(1)(A). Where Congress has required a party to seek immediate judicial review, the case is ripe for adjudication whenever the issues meet the first prong of the *Abbott Labs* test. *See Ohio Forestry Ass'n, Inc. v. Sierra Club*, 523 U.S. 726, 737 (1998) (identifying TSCA as a statute "that Congress has specifically instructed the courts to review 'preenforcement'"); *Gen. Elec. Co.*, 290 F.3d at 381.

If the Court were to consider hardship, this factor would weigh in favor of immediate review. NRDC's members are being harmed by the increased risk of exposure to adverse health effects from EPA's failure to implement the section 5 review process, and the legal questions presented by this petition for review are capable of resolution now. *See Nat'l Envtl. Dev. Assoc.'s Clean Air Project v. EPA*, 752 F.3d 999, 1008 (D.C. Cir. 2014). ("Petitioner's challenge in this case presents a purely legal question [and] . . . [i]t is unnecessary to wait for the [agency directive] to be applied in order to determine its legality.").

II. The Framework Rule contradicts TSCA's requirements and was issued without following mandatory procedures

The Framework Rule violates two basic principles of administrative law, each of which provides an independent ground for setting it aside: (A) the Framework Rule is contrary to the plain language of section 5 of TSCA; and (B) the Agency adopted the Framework Rule—which is a legislative rule with immediate legal effects—without notice and comment.

A. The Framework Rule is contrary to section 5 of TSCA

The Framework Rule contradicts the plain meaning of TSCA. EPA limits its review of a new chemical substance to the manufacturer's intended conditions of use and disregards Congress's instruction to address risk concerns through enforceable orders and regulations. In interpreting a statute, "[f]irst, always, is the question whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. It has. TSCA states that if EPA determines that a chemical substance presents an unreasonable risk, or that it may present an unreasonable risk, then EPA "shall" issue an order under section 5 "to prohibit or limit" the use of the new chemical substance to the extent necessary to protect against an unreasonable risk. 15 U.S.C. § 2604(a)(3)(A)-(B), (e)(1)-(3), (f)(1)-(3). "The use of the word 'shall' makes the action mandatory." *Salazar v. King*, 822 F.3d 61, 77 (2d Cir. 2016). Nothing in section 5 permits EPA to substitute a significant new use rule for an order or regulation restricting manufacture.

EPA can avoid issuing an order under section 5(e) or section 5(f) only if it makes an affirmative finding that a new chemical substance "is not likely to present an unreasonable risk." 15 U.S.C. § 2604(a)(3)(C). That finding must be based on an evaluation of the

chemical under its "conditions of use," *id.*, defined to include the circumstances "under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." *Id.* § 2602(4). Nothing in section 5 permits EPA to use a significant new use rule to defer its review of *all* of the conditions of use. Congress has directed EPA to undertake a comprehensive review of new chemical substances under the full spectrum of their conditions of use, and EPA is not free to depart from that structure for its own convenience, or for the convenience of chemical manufacturers.

The Framework Rule also ignores the structure of section 5. "A particular statute's 'plain meaning can best be understood by looking to the statutory scheme as a whole and placing the particular provision within the context of that statute.'" *Louis Vuitton Malletier S.A. v. LY USA, Inc.*, 676 F.3d 83, 108 (2d Cir. 2012) (*quoting Saks v. Franklin Covey Co.*, 316 F.3d 337, 345 (2d Cir. 2003)); *see also FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 133 (2000) ("[T]he words of a statute must be read in their context and with a view to their place in the overall statutory scheme" (internal quotation marks omitted)). As other portions of section 5 make clear, Congress did not intend for

significant new use rules to substitute for section 5 orders, or for EPA to issue "not likely to present" determinations based on the prospect of later-issued significant new use rules. Significant new use rules are supposed to follow the issuance of consent orders. Section 5(f)(4) of TSCA directs that "not later than 90 days after . . . issuing an order under subsection (e) relating to a chemical substance," EPA "shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any" uses "of the chemical substance that do[] not conform to the restrictions imposed by the . . . order." 15 U.S.C. § 2604(f)(4). Significant new use rules are thus intended to complement, and not to substitute for, orders under section 5(e). Nothing in the structure of section 5 permits the approach that EPA has adopted.

Further, EPA's no-order policy is inconsistent with TSCA's definition of "conditions of use," and with the way that phrase is employed throughout section 5. Congress adopted a broad definition of "conditions of use," and required that determinations about chemical safety be based on a review of those conditions of use. *Id.* §§ 2602(4), 2604(a)(3). This definitional provision centers new chemical reviews on a comprehensive risk evaluation, rather than a piecemeal

review limited to a particular set of intended conditions of use. *See id.* § 2604(a)(3)(B)(ii)(I) (permitting regulation where "the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment.").

Indeed, other parts of section 5 demonstrate that, where Congress intended EPA to conduct a narrower review, it used language to that effect. For example, section 5(h) of TSCA allows EPA to approve a test marketing exemption for a new chemical substance based on "the specific conditions of use identified in the application." *Id.* § 2604(h)(1)(A). This language "shows that when Congress intended to authorize" a determination based on something less than the full conditions of use, "it knew how to do so." *Custis v. United States*, 511 U.S. 485, 492 (1994); *see also Russello v. United States*, 464 U.S. 16, 23 (1983) ("Where Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." (quotation omitted)).

EPA's stated intention to use the approach outlined in the Framework Rule to "defer further analysis of reasonably foreseen

conditions of use until such time as the submitter (or any other entity) actually intends to undertake them,"[8] is inconsistent with TSCA's requirement that in implementing section 5, "the Administrator shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to the Administrator." 15 U.S.C. § 2625(k). The Framework Rule limits the use of "reasonably available" information; in fact, it permits EPA to disregard information about risk concerns based on reasonably foreseen conditions of use, and determine, without that information, that the new chemical substance does not present a risk to public health or the environment. The Framework Rule cannot be squared with the statute.

The legislative history of TSCA demonstrates that the Framework Rule is an impermissible rewriting of section 5. It suffices that the Framework Rule contradicts the text and structure of TSCA. Nevertheless, the Court may also consult the statute's legislative

[8] Actions Under TSCA Section 5: SNURs for New Chemicals, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs (last visited May 1, 2018).

history to the extent it sheds light on the meaning of the statute. *See United States v. Epskamp*, 832 F.3d 154, 162, 165 (2d Cir. 2016).

The legislative history unequivocally shows that Congress intended to enact a comprehensive risk review for new chemicals, and that EPA is compromising that process through the Framework Rule. According to the statement of intent submitted by the lead Senate Democratic negotiators of the Lautenberg Chemical Safety Act, the purpose of the amendments to section 5 was to "require[]" EPA "to review all new chemicals and significant new uses and make an affirmative finding regarding the chemical's or significant new use's potential risks. . . . [I]n the absence of a finding that the chemical or significant new use is not likely to present an unreasonable risk, manufacture will not be allowed to occur." 162 Cong. Rec. S3511-01, S3516 (daily ed. June 7, 2016). Only after EPA has analyzed the *potential* risks of the new chemical and found that it is not likely to present an unreasonable risk can the new chemical "enter production without restriction." *Id.* The same statement in the legislative history noted that the new definition of "conditions of use" "provides . . . a mandate for EPA to consider conditions of use that are not currently known or intended but can be anticipated to occur." *Id.* Senator Vitter, a

sponsor of the Lautenberg Chemical Safety Act, further noted that the language in section 5 was the result of a "compromise" that "requires EPA [to] regulate the new chemical to the extent necessary to protect against unreasonable risk" whenever "EPA does not have the information sufficient for the evaluation of a new chemical." *Id.* at S3520.

Both Senator Vitter and the other negotiators emphasized that the purpose of the section 5(e) requirements was to provide EPA with authority to require additional testing to address risk concerns. *Id.* at S3516 ("EPA can also require additional testing."); *id.* at S3520 ("Once sufficient information is available, of course, EPA must make a decision."); *see also id.* at S3513 (statement of Sen. Udall). The Framework Rule forfeits this authority: If EPA has "concerns" about reasonably foreseen uses, it will not issue an order under section 5(e), and will not take advantage of this testing authority. *See* New Chemicals Decision-Making Framework at 2.[9]

[9] *See also* Actions Under TSCA Section 5: SNURs for New Chemicals, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/actions-under-tsca-section-5#SNURs (last visited May 1, 2018).

The no-order policy is not adequately protective of public health or the environment. Section 5 orders and significant new use rules are meaningfully distinct. Section 5 orders are effective immediately; identify companies subject to the order; impose specific conditions restricting a chemical's manufacture, processing, or distribution; and can be reopened if additional testing compels EPA to impose more stringent conditions. Significant new use rules have none of those features.

First, a section 5 order takes effect "on the expiration of the applicable review period." 15 U.S.C. § 2604(e); *see also id.* § 2604(f)(3)(A) (order under section 5(f) becomes effective immediately). Regulations issued under EPA's authority in section 5(f) also take effect once they are proposed, and must be published prior to the expiration of EPA's review period. *Id.* § 2604(f)(1)-(2). A significant new use rule, on the other hand, must be promulgated through the notice and comment process, unless EPA is able to take advantage of direct final rulemaking. *See* 40 C.F.R. § 721.160. Further, there is no legally binding timetable for EPA to promulgate a significant new use rule, unless EPA has already issued a section 5(e) or section 5(f) order for a new chemical substance. Even if, under the Framework Rule, EPA

intends to issue a significant new use rule simultaneously with its "not likely to present an unreasonable risk" determination, there are good reasons to believe that EPA will not meet such a self-imposed deadline. First, EPA is already far behind on the process of issuing significant new use rules required by section 5(f)(4) of TSCA. In October 2017, for example, EPA promulgated 29 significant new use rules for new chemicals for which it had issued consent orders; many of these consent orders dated back to January or February 2017. *See* 82 Fed. Reg. 48637 (Oct. 19, 2017). Second, a significant new use rule can become immediately effective only if EPA takes advantage of direct final rulemaking. *See* 40 C.F.R. § 721.160(c). If anyone wishes to submit adverse or critical comments, however, the significant new use rule does not become effective under the direct final rulemaking provisions. *Id.* § 721.160(c)(3). In the meantime, unlike with a section 5 order, the public is unprotected.

Second, section 5 orders are binding on the specific companies subject to them, and information about the orders must be provided in workplaces where activities subject to the consent order are taking place. *See* Sample EPA Consent Order, Section II, Hazard

Communication Program.[10] Thus, EPA can determine whether companies subject to the consent orders are abiding by the conditions incorporated by those orders. By contrast, a significant new use rule requires only notification: A company wishing to undertake a significant new use must file a notification (known as a significant new use notification). *See* 40 C.F.R. § 721.25(a). EPA must then decide whether to permit the new use, or to issue an order restricting it. *See* 15 U.S.C. § 2604(a)(2). But EPA has little means to determine whether a manufacturer has undertaken a significant new use without the manufacturer's first providing notification.

Third, a section 5 order must meet a statutorily prescribed standard: it must impose conditions "to the extent necessary to protect against an unreasonable risk of injury to health or the environment," and cannot be based on consideration of costs. *Id.* § 2604(e). There is no similar requirement for the level of protection that EPA must provide in a significant new use rule. Further, EPA can require testing on specific environmental and health risks in a section 5 order. *See id.* There is no

[10] https://www.epa.gov/sites/production/files/2016-09/documents/co_all_purpose_preamble_and_consent_order_combined_9-1-2016_clean.pdf (last visited May 1, 2018).

such authority with a significant new use rule. Hence, where EPA has risk concerns with reasonably foreseen uses of a new chemical substance, a section 5 order can require testing to evaluate those concerns, while a significant new use rule does not. Further, a section 5 order can be used to hold a manufacturer to the conditions of use described in the premanufacture notice. So, for example, if a company's intended conditions of use include the use of safety equipment like respirators or contamination suits, EPA can issue a section 5 order mandating the use of that equipment. However, EPA regulations provide that a significant new use rule can apply only to uses that are not presented in the premanufacture notice. *See* 40 C.F.R. § 721.170(c)(2). Thus, such rules are not a means by which EPA can require a manufacturer to follow its outlined conditions of use.

Finally, a section 5 order can be reopened if subsequent testing reveals that EPA has underestimated the degree of health or environmental risk presented by a chemical. *See* Sample EPA Consent Order, Section II(j).[11] A significant new use rule, however, cannot be

[11] https://www.epa.gov/sites/production/files/2016-09/documents/co_all_purpose_preamble_and_consent_order_combined_9-1-2016_clean.pdf (last visited May 1, 2018).

reopened in the same way. Once promulgated, it is subject to modification only by the issuance of another rule, a potentially lengthy process during which the public will also remain unprotected.

Orders and regulations issued pursuant to EPA's authority under section 5(e) and section 5(f) of TSCA contain robust protections for human health and the environment. Significant new use rules are not a substitute for them.

B. The Agency violated the APA by promulgating the Framework Rule without notice and comment

EPA did not follow the notice and comment procedure.

EPA failed to provide notice and an opportunity for comment before issuing the Framework Rule and thus acted "without observance of procedure required by law." 5 U.S.C. § 706(2)(D). This failure alone justifies vacating the Framework Rule.

Under the APA, an agency must provide the public with "[g]eneral notice of proposed rule making," as well as "an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id.* § 553(b)-(c). Notice and comment "serve the need for public participation in agency decisionmaking" and "ensure the agency has all pertinent information before it when making a decision."

Time Warner Cable Inc. v. Fed. Commc'ns Comm'n, 729 F.3d 137, 168 (2d Cir. 2013) (internal quotation marks omitted).

The Framework Rule was posted to EPA's website. *See* New Chemicals Decision-Making Framework. EPA published a Federal Register notice concerning the Framework Rule on November 6, 2017. *See New Chemicals Review Program Implementation and Approaches for Identifying Potential Candidates for Prioritization for Existing Chemical Risk Evaluations Under the Amended Toxic Substances Control Act; Notice of Public Meetings and Opportunity for Public Comment*, 82 Fed. Reg. 51415 (Nov. 6, 2017). This notice was not published as a notice of proposed rulemaking; it did not include the text of the Framework Rule, and, while it invited public comment on the topics covered by the Framework Rule, EPA did not announce any intention to respond to those comments in a final rulemaking. *See id.* Further, EPA treated the Framework Rule as "governing" its review of premanufacture notices once it was issued, without responding to public comments or publishing a further final rule. *See supra* pp. 20-21.

EPA thus has not followed any step of the "three-step procedure for so-called 'notice-and-comment rulemaking.'" *Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1203 (2015). EPA has not "issue[d] a '[g]eneral

notice of proposed rule making.'" *Id.* (quoting 5 U.S.C. § 553(b) (first alteration added, second alteration in original)). Prior to adopting the Framework Rule, EPA did not "consider and respond to significant comments received during the period for public comment." *Id.* And finally, EPA did not "include in the rule's text 'a concise general statement of [its] basis and purpose.'" *Id.* (quoting 5 U.S.C. § 553(c) (alteration in original)).

Notice and comment was required. The Framework Rule is a legislative rule that EPA could adopt only through the process prescribed by the APA. "A legislative rule modifies or adds to a legal norm," and "creates new rights or imposes new obligations on regulated parties or narrowly limits administrative discretion." *Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710, 716-17 (D.C. Cir. 2015) (emphasis and internal quotation marks omitted); *see also White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993) (A legislative rule "create[s] new law, rights, or duties in what amounts to a legislative act."). Further, "[a]n agency action that sets forth legally binding requirements for a private party to obtain a permit or license is a legislative rule." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 251-52 (D.C. Cir. 2014). In this case, the Framework Rule "outlines EPA's

approach to making decisions on new chemical notices," New Chemicals Decision-Making Framework at 1, and thus the circumstances under which EPA will allow a new chemical substance to be used in commercial applications.

The Framework Rule modifies a legal norm established by TSCA by granting EPA discretion to approve the unrestricted manufacture of new chemical substances in circumstances where the statute itself forbids it. TSCA uses mandatory language: if the information available to EPA "is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance," or "in the absence of sufficient information to permit the Administrator to make such an evaluation" of whether the substance may present a risk "under the conditions of use," then EPA "*shall* issue an order . . . to prohibit or limit" the commercial use of that chemical "to the extent necessary to protect against an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(e)(1)(A) (emphasis added).

Part II.A explained that TSCA does not permit EPA to limit its review of the conditions of use to the "intended conditions of use as described in a submission (original or amended)." New Chemicals Decision-Making Framework at 2. It follows that "[w]here EPA has

concerns with reasonably foreseen conditions of use," *id.*, it may not approve the unrestricted manufacturing of that substance and subsequently "address such concerns through SNURs." New Chemicals Decision-Making Framework at 2. The Framework Rule, however, establishes a baseline that EPA will do just that. *Id.*

A decision to implement a regulatory process that departs from the governing statute is the sort of "binding change in the law" that can be accomplished (if at all) only through notice and comment rulemaking. *See NRDC v. EPA*, 643 F.3d 311, 319, 321 (D.C. Cir. 2011). In the D.C. Circuit's *NRDC* decision, EPA issued a purported "guidance" document to regional clean air directors allowing them to approve, for regions exceeding the Clean Air Act's limits on ozone in the ambient air, either "the statutorily mandated program" or "an equivalent . . . program alternative" defined in the guidance. *Id.* at 317. Additionally, a region could avoid paying fees for non-compliance set forth in the Clean Air Act by meeting an "attainment alternative," also set forth in the guidance. *Id.* By informing regional air directors that it was permissible to consider alternatives for non-compliant areas, the guidance document "has definitively interpreted [the statute] as permitting alternatives." *Id.* at 320. The D.C. Circuit had little trouble

concluding that this "guidance" document should have been issued through the notice and comment process. *Id.* at 320-21 ("Given that the Guidance document changed the law, the first merits question—whether the Guidance is a legislative rule that required notice and comment—is easy.").

Here, the Framework Rule informs regulated parties and the general public that the Toxics Office will: (1) restrict its review of intended conditions of use to the intended conditions presented in the most recently amended premanufacture notice, and (2) will not issue an order under section 5(e) or section 5(f) where the Toxic Office has risk concerns based on reasonably foreseen conditions of use. New Chemicals Decision-Making Framework at 2. Instead, EPA's "expectation is that SNURs will generally be effective vehicles to address such concerns and that, as a general matter, EPA will address such concerns through SNURs." *Id.* EPA's repetition of the word "generally" in that sentence does not make this any less of a binding change in the law. In the D.C. Circuit's *NRDC* decision, a binding change in the law occurred because the guidance *permitted* the consideration of alternatives. *NRDC*, 643 F.3d at 320. So too here, the

Framework Rule *permits* EPA to follow an approval process that is less protective of public health than the process established by TSCA.

The Framework Rule was not exempt from notice and comment as either an interpretive rule or a general statement of policy. *See* 5 U.S.C. § 553(b)(3)(A), (d)(2). The Framework Rule does not purport to "interpret" either TSCA itself or an EPA regulation issued pursuant to TSCA. Unlike an interpretive rule, it created a binding change in the law. *See United States v. Yuzary*, 55 F.3d 47, 52 (2d Cir. 1995) ("'A rule is interpretive . . . if it attempts to clarify an existing rule but does not change existing law, policy, or practice.'") (quoting *Rocky Mountain Helicopters, Inc. v. FAA*, 971 F.2d 544, 546-47 (10th Cir. 1992)). Nor does the Framework Rule qualify as a "general statement of policy." "General statements of policy are statements issued by an agency to advise the public prospectively of the manner in which the agency proposes to exercise a discretionary power." *Chrysler Corp.*, 441 U.S. at 302 n.31 (internal quotation marks omitted). The premanufacture review process for new chemicals, however, is not a discretionary power of EPA. It is instead subject to the requirements of section 5 of TSCA—including the new requirements of the Lautenberg Chemical Safety Act.

The Framework Rule is thus a legislative rule, and could be adopted only after notice and comment.

It is immaterial that EPA opened a docket to accept public comment on the Framework Rule after it was issued. "[N]otice and an opportunity for comment are to precede rule-making. . . . [P]ost hoc comment was not contemplated by the APA and is generally not consonant with it." *State of N.J., Dep't of Envtl. Prot. v. EPA*, 626 F.2d 1038, 1050 (D.C. Cir. 1980); *see also Abraham*, 355 F.3d at 206 & n.14. EPA has not committed to issuing the Framework Rule as a final rule, or committed to publishing a statement in the Federal Register responding to comments. The agency's vague assurance that it will use public comment "to improve policy and processes relating to the review of new chemicals under TSCA" has no legal significance and does not remedy the procedural violations. 82 Fed. Reg. at 51,415, EPA-R-021, JA__.

Finally, while the Court could vacate the Framework Rule and remand it to EPA based solely on EPA's failure to accept pre-promulgation public comment, principles of judicial economy argue in favor of addressing the Framework Rule's substantive failures as well. *See NRDC*, 643 F.3d at 322 (addressing merits of EPA's interpretation

after finding procedural deficiencies, because EPA's interpretation "violates the statute's plain language," and "nothing would be gained by postponing a decision on the merits"). Congress had compelling reasons for enacting a section 5 review process that requires EPA to undertake a comprehensive review of new chemical substances before they enter the market. EPA may not rewrite those protections for the sake of expediency, either for itself or for the industries it is supposed to be regulating.

III. NRDC has standing

An organization has standing to sue on behalf of its members when: (1) the interests at stake are germane to the organization's purpose, (2) the lawsuit does not require participation of individual members, and (3) the organization's members would have standing to sue in their own right. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 181 (2000).

Petitioner NRDC satisfies this test. It is committed to reducing or eliminating toxic chemicals that pose a threat to public and environmental health. Decl. of Gina Trujillo ¶¶ 6-8. Neither the claims asserted in this petition nor the relief requested require the participation of individual NRDC members, because NRDC is not

seeking individualized relief. *Laidlaw*, 528 U.S. at 181. And, as explained below, NRDC's members would have standing to challenge the Framework Rule in their own right because they have demonstrated an "injury in fact" that is "fairly traceable" to the unlawfully promulgated rule and is "likely" to be "redressed by a favorable decision." *Id.* at 180-81.

Injury-in-fact: NRDC's members are harmed by the risk of exposure to toxic chemicals that results from EPA's refusal to engage in the required review process for new chemical substances. EPA makes risk determinations on hundreds of chemicals every year through the premanufacture review process; the average number of premanufacture notices pending at the end of 2017 and the beginning of 2018 varied between 400 and 500 new chemicals.[12] From August 2016 to November 2017, EPA used its authority under the 2016 TSCA amendments to issue 109 consent orders governing 291 new chemical substances. *See* Add. 34, Decl. of Mark C. Segal ¶ 8. These consent orders demonstrate the range of public health and environmental risks presented by new

[12] Statistics for the New Chemicals Review Program Under TSCA, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review (last visited May 1, 2018).

chemical substances. Out of 239 premanufacture notices that contained information about exposed populations, over 120 of these chemicals had exposure risks for the general population. *Id.* ¶ 18. These risks arose from environmental contamination, water contamination, or, in the case of flame-retardant chemicals, consumer exposure to the chemicals. *Id.* ¶¶ 18-20. The health concerns arising from exposure to these chemicals included toxicity, lung damage, cancer and developmental effects, neurological effects, reproductive effects, and damage to internal organs. *Id.* ¶ 19. This review of consent orders issued after the 2016 amendments and before the adoption of the Framework Rule confirms that chemical exposure occurs under conditions throughout the manufacturing, processing, or distribution chain. *See supra* pp. 10-12.

EPA makes hundreds of determinations every year under the section 5 process, and the Agency's failure to follow the process required by TSCA exposes NRDC's members to a heightened risk of adverse health effects from these chemicals. NRDC's addendum presents three declarations from members who are anxious about chemical exposure for themselves and their families. Diane Brenum suffers from chemical sensitivities, which have caused adverse health effects. Add. 27, Decl. of

Diane Brenum ¶¶ 3-4. Further, she is unable to completely control her exposure to environmental chemicals, and frequently suffers adverse health effects from exposure to chemicals in public places. *Id.* ¶¶ 8-9.

Similarly, Maria Ayers and her children suffer adverse health effects, such as rashes or other skin conditions, after exposure to chemicals. Add. 13, Decl. of Maria Ayers ¶¶ 4-5. Like Ms. Brenum, Ms. Ayers is unable to completely control the chemicals to which she and her children are exposed, and they suffer adverse reactions from these exposures. *Id.* ¶¶ 8-10. Ms. Ayers is also worried about the long-term effects of chemical exposure on the environment and water quality. *Id.* ¶ 11.

Finally, Thomas Ayres is concerned about the chemicals to which he is exposed, and to which other members of his family are exposed, including his grandchildren and a brother who works in the construction trade. Add. 20, Decl. of J. Thomas Ayres ¶¶ 4-8, 12. Mr. Ayres also serves on his local water board, and is thus aware of the risk that environmental toxicity presents to water supplies. *Id.* ¶¶ 10-11. Mr. Ayres' declaration also recounts the ways in which his health has suffered from exposure to environmental chemicals. *Id.* ¶ 7.

These members are injured by EPA's failure to comprehensively review the health and environmental risks posed by new chemical substances.[13] This Court recognizes that "threatened harm in the form of an increased risk of future injury may serve as injury-in-fact for Article III standing purposes." *Baur v. Veneman*, 352 F.3d 625, 633 (2d Cir. 2003). The threatened harm here is simple: Under the Framework Rule, new chemical substances that present "concerns" under "reasonably foreseen conditions of use," New Chemicals Decision-Making Framework at 2, will not be subject to an enforceable order under section 5 restricting their manufacture, as required by TSCA. Instead, EPA will be relying on non-enforceable significant new use rules for those chemical substances. EPA's acknowledgement that it will use the Framework Rule to address its "risk concerns" with reasonably foreseen conditions of use is evidence that NRDC's members will be

[13] These members are also procedurally injured by their inability to comment on the Framework Rule before it was issued. *See* Decl. of Maria Ayers ¶ 12; Decl. of J. Thomas Ayres ¶ 13; Decl. of Diane Brenum ¶¶ 12-14. NRDC regularly files comments on public health issues like EPA's administration of TSCA. *See* Decl. of Gina Trujillo ¶¶ 6-8; *see also Cmts. of Safer Chemicals Healthy Families, et al., on Improvements to the New Chemicals Review Program under the Amended Toxic Substances Control Act* (Jan. 17, 2017), EPA-HQ-OPPT-2016-0658-0033, JA __ (comment submitted by NRDC).

facing potential exposure to substances with health and environmental risks. *See Baur*, 352 F.3d at 637-40 (government statements acknowledging risk of harm "weigh in favor of concluding that standing exists"). This risk of exposure is injury-in-fact that satisfies Article III.[14] *See NRDC v. FDA*, 710 F.3d 71, 81 (2d Cir. 2013), as amended (Mar. 21, 2013) ("[T]he injury contemplated by exposure to a potentially harmful product is not the future harm that the exposure risks causing, but the present exposure to risk."); *N.Y. Pub. Interest Research Grp. v. Whitman*, 321 F.3d 316, 326 (2d Cir. 2003) ("[T]he distinction between an alleged exposure to excess air pollution and uncertainty about exposure is one largely without a difference since both cause personal and economic harm.").

NRDC's standing is reinforced by the close connection between its members' injuries and the purposes of the statute. As amended, TSCA

[14] EPA often withholds even basic information about new chemical substances as confidential business information, and thus there is no reliable way for NRDC's members to reduce or mitigate their exposure by avoiding certain products or brands. *See, e.g.*, TSCA Section 5(a)(3)(C) Determination for Premanufacture Notice (PMN) P-18-0026, https://www.epa.gov/sites/production/files/2018-01/documents/p-18-0026_determination_non-cbi_final.pdf (withholding the name of the manufacturer of the substance or the facilities where it will be manufactured, processed, or distributed) (last visited May 1, 2018).

explicitly requires EPA to consider the effects of a new chemical substance on a "potentially exposed or susceptible subpopulation." 15 U.S.C. § 2604(a)(3). As examples of such subpopulations, Congress identified "infants, children, pregnant women, workers, or the elderly." *Id.* § 2602(12). Among NRDC's members are individuals who fall within these groups, and who are legitimately concerned about their risk of exposure to new chemicals approved under the Framework Rule. *See* Decl. of J. Thomas Ayres ¶ 3 (explaining that Mr. Ayres is 71 years old, and retired from a career in construction); Decl. of Maria Ayers ¶¶ 4-5 (explaining the risks that chemicals present to her children's health). TSCA targets the heightened risks these members face from exposure to toxic chemicals, which further supports Article III standing. *See Baur*, 352 F.3d at 635 ("[T]here is a tight connection between the type of injury which [plaintiff] alleges and the fundamental goals of the statutes which he sues under—reinforcing [plaintiff's] claim of cognizable injury").

Causation and redressability: Increased exposure to toxic chemicals is fairly traceable to the Framework Rule because the Agency ignored statutory requirements designed to ensure comprehensive review of the risks of new chemical products. Were EPA to issue

enforceable orders to address the Agency's concerns with the environmental and health risks presented by new chemical substances, then NRDC's members would not face the same health and environmental risks from those substances. *See Baur*, 352 F.3d at 632 & n.6; *Carpenters Indus. Council v. Zinke*, 854 F.3d 1, 6 (D.C. Cir. 2017) (when "predicting . . . causal effects" for standing, "common sense can be a useful tool").

The increased exposure to harmful chemicals would also likely be redressed by a favorable decision for essentially the same reasons. *See id.* at 6 n.1. Vacating the Framework Rule and requiring EPA to issue section 5 orders to address health and environmental risks presented by a chemical substance's conditions of use is likely to reduce the risks faced by susceptible subpopulations and the general public. *See* 15 U.S.C. § 2604(e) (orders must "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or . . . prohibit or limit any combination of such activities *to the extent necessary to protect against an unreasonable risk of injury to health or the environment*." (emphasis added)). Risks such as these, which stem from the Agency's failure to administer TSCA's new chemicals program in accordance with the statute's requirements, are sufficient to establish

causation and redressability. *See N.Y. Pub. Interest Research Grp.*, 321 F.3d at 326 (holding that "allegations of administrative failure . . . are also sufficient to establish causation, as the exposure to potentially excessive pollutants will likely be redressed by a favorable decision").

CONCLUSION

Congress amended TSCA to augment protections from exposures to toxic chemicals. These protections specifically targeted individuals—children, the elderly, pregnant women, and workers—who are most susceptible to harm. Through the Framework Rule, without benefit of public participation, EPA attempts to sidestep these increased safeguards and make it easier for manufacturers to introduce chemicals that pose foreseeable risks. For the foregoing reasons, the Court should vacate the Framework Rule.

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

Pursuant to Federal Rule of Appellate Procedure 32(g), I certify that this Opening Brief complies with the type-volume limitations of Second Circuit Rule 32.1(a)(4)(A) because it contains 11,371 words, excluding parts of the document exempted by Rule 32(f).

Dated: May 1, 2018

/s/Thomas Zimpleman
Thomas Zimpleman

CERTIFICATE OF SERVICE

I hereby certify that I electronically filed the foregoing with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system on May 1, 2018.

I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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