18-25

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL,

Petitioner,

SAFER CHEMICALS HEALTHY FAMILIES,

Intervenor,

—v.—

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent,

AMERICAN CHEMISTRY COUNCIL,
NATIONAL ASSOCIATION OF MANUFACTURERS,

Intervenors.

ON PETITION FOR REVIEW OF AGENCY ACTION OF THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

BRIEF FOR INTERVENORS AMERICAN CHEMISTRY COUNCIL AND NATIONAL ASSOCIATION OF MANUFACTURERS

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Dated: August 14, 2018

/s/ *Allison Wisk Starmann*
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Dated: August 14, 2018

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STATEMENT OF THE ISSUES PRESENTED

1. Have Petitioner and Intervenor Safer Chemicals Healthy Families met jurisdictional requirements for judicial review of the draft Framework Document where Article III standing requirements have not been met, there is no "final rule" at issue, and the case is not ripe for review?
2. Does the Administrative Procedure Act's notice and comment requirement apply to EPA's issuance of the draft Framework Document, which creates no legal rights or obligations?
3. Is the draft Framework Document consistent with TSCA, which confers on EPA discretion to determine whether a new chemical substance is likely to present unreasonable risk under its conditions of use?

STATEMENT OF THE CASE

This case involves an EPA document entitled "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" (Nov. 2017). Natural Resources Defense Council (Petitioner) and Safer Chemicals Healthy Families (Intervenor SCHF) refer to this document as the "Framework Rule" or the "Framework." This brief refers to it as the "draft Framework Document." EPA posted the draft Framework Document on its website on November 7, 2017, explaining it is a draft, one day after announcing a public meeting and opportunity for comment on how EPA should implement

section 5 of the Toxic Substances Control Act (TSCA) as amended on June 22, 2016. The draft Framework Document indicates generally how EPA may implement amended section 5.

The following provides an explanation of the statutory provisions of amended section 5, followed by a summary of the draft Framework Document.

A. Review of Key Provisions of TSCA

TSCA was enacted in 1976[1] and amended in 2016.[2] The 2016 amendments revised section 5, 15 U.S.C. § 2604, in some ways while retaining key aspects of the original provision.

1. The New Chemical Review Process

TSCA governs certain aspects of "chemical substances," a term defined in part to exclude pesticides and FDA-regulated chemicals. TSCA section 3(2), 15 U.S.C. § 2602(2). Under section 8(b)(1), 15 U.S.C. § 2607(b)(1), EPA was required to establish an Inventory of Existing Chemical Substances (the Inventory), which it did in 1979. Anyone may manufacture[3] a substance on the Inventory (known as an existing chemical substance), subject to any restrictions EPA may have imposed.

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[1] Toxic Substances Control Act, Pub. L. No. 94-469, 90 Stat. 2003 (Oct. 11, 1976).
[2] Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182 (June 22, 2016), 130 Stat. 448.
[3] The term "manufacture" includes "import." Section 3(9), 15 U.S.C. § 2602(9).

The Inventory includes a confidential portion and a nonconfidential portion. Section 8(b)(4)(B)(i), 15 U.S.C. § 2607(b)(4)(B)(i). The nonconfidential portion shows specific chemical identities for substances on the Inventory that were not claimed to be protected from disclosure under the confidential business information provisions of section 14, 15 U.S.C. § 2613. It is publicly accessible on EPA's website. The confidential portion, which is not publicly accessible, contains specific chemical identities for substances on the Inventory that were claimed to be protected from disclosure under section 14. EPA posts on its website a public version of the confidential Inventory containing only generic names for those substances. Declaration of Michael P. Walls (Walls Decl.) ¶ 36.

A chemical substance not included on the Inventory is deemed to be a new chemical substance. Section 3(11), 15 U.S.C. § 2602(11). Section 5(a)(1)(A)(i), 15 U.S.C. § 2604(a)(1)(A)(i), prohibits any person from manufacturing a new chemical substance for non-exempt purposes except as provided under section 5(a)(1)(B).[4] Under section 5(a)(1)(B), however, a prospective manufacturer may submit an application to EPA, known as a premanufacture notice (PMN), to enable EPA to conduct a risk review for the substance under its conditions of use. The PMN describes the conditions of use intended by the submitter. After completing

[4] Exempt purposes include, for example, manufacture as an impurity or for research and development purposes. 40 C.F.R. § 720.30.

its review, EPA may or may not authorize the PMN submitter to begin non-exempt manufacture. EPA's process for reviewing PMNs is known as the New Chemicals Review Process.

Unlike other statutory provisions, section 5 does not mandate that EPA adopt any regulations or guidance to implement the New Chemicals Review Process. For the first four years after TSCA's initial enactment (July 1, 1979 to October 25, 1983), the New Chemicals Review Process operated without any regulations. In 1983, EPA adopted regulations in 40 C.F.R. Part 720 limited to procedural matters. It has never adopted regulations regarding implementation of the New Chemicals Review Process. EPA has always implemented the New Chemicals Review Process on the basis of section 5 itself. Walls Decl. ¶ 22.

Section 5(d), 15 U.S.C. § 2604(d), and regulations at 40 C.F.R. Part 720, Subpart C, prescribe the information that a PMN must contain. Required information includes, among other things, the anticipated uses, anticipated production volume, engineering controls to prevent unintended releases, personal protective equipment to be worn by employees, release points, waste treatment, disposal method, and number of individuals potentially exposed.

EPA has 90 days by statute to review the PMN, a period which may be extended for up to 90 additional days pursuant to section 5(c).

15 U.S.C. § 2604(c). EPA's regulations allow EPA to suspend the running of the 90-day period with the agreement of the PMN submitter. 40 C.F.R. § 720.75(b).

Under section 5(a)(3), 15 U.S.C. § 2604(a)(3), EPA must make a risk determination for the PMN substance. The determination must be based solely on any risk to health and the environment, without regard to cost or other non-risk factors. EPA must make its risk determination under the PMN substance's "conditions of use." This term is defined in section 3(4), 15 U.S.C. § 2602(4), to mean "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."

In evaluating a PMN and other relevant information, EPA may identify concerns. EPA evaluates those concerns in making a risk determination. Walls Decl. ¶¶ 20-21.

Under section 5(a)(3), EPA may make any of several determinations. EPA Brief at 5-6. The two of most interest here are: (1) the substance "is not likely to present an unreasonable risk" or (2) the substance "may present an unreasonable risk."

If EPA makes a "not likely to present" determination, it must make a public statement of that finding. The PMN submitter may then begin non-exempt[5] manufacture of the substance immediately. Section 5(g), 15 U.S.C. § 2604(g).

If EPA makes a "may present" determination, EPA must issue an order under section 5(e). The order must prohibit or restrict activities related to the substance "to the extent necessary to protect against an unreasonable risk …." Section 5(e), 15 U.S.C. § 2604(e). At the end of the PMN review period "the submitter of the notice" may begin non-exempt manufacture of the substance, but "only in compliance with the order." *Id.* At this point, the PMN submitter is the only entity bound by the section 5(e) order.

Once the PMN review period ends, the PMN submitter may begin non-exempt manufacture of the PMN substance. Within 30 days of doing so, it must submit a notice to EPA, known as a notice of commencement of manufacture or import (Notice of Commencement), providing the date of first non-exempt manufacture. 40 C.F.R. § 720.102; Walls Decl. ¶ 27. After receiving a Notice of Commencement, EPA will add the substance to the Inventory. Once that happens, the substance becomes an existing chemical substance that any other person may manufacture or process, subject to any applicable restriction.

[5] "Non-exempt" means not eligible for a TSCA exemption. As noted *supra*, exemptions include manufacture as an impurity or for research and development purposes. 40 C.F.R. § 720.30.

2. Significant New Use Rules

Congress recognized that the PMN submitter might change its conditions of use from those described in the PMN. Congress also recognized that other manufacturers or processors of the substance (once added to the Inventory) might change or add to the conditions of use presented by the PMN submitter. The mechanism for addressing these changed or new conditions of use after submission of the Notice of Commencement is known as a significant new use rule (SNUR).

A SNUR applies to one or more chemical substances identified in the rule. Almost all SNURs are for PMN substances that are going through or have completed the New Chemicals Review Process.[6]

A SNUR designates certain activities as significant new uses for a particular chemical substance. A SNUR prohibits any person from engaging in those significant new uses without first obtaining EPA's authorization to do so. That authorization, if it comes at all, may be conditioned on compliance with a section 5(e) order.

Significant new uses are generally activities that relate to protection of health or the environment. They are typically worded as uses without a specified

[6] A few SNURs apply to chemical substances that have been on the Inventory for many years but whose uses are declining. Examples include SNURs for certain perfluoroalkyl sulfonates, 40 C.F.R. § 721.9582, and for elemental mercury, 40 C.F.R. § 721.10068.

protection. For instance, a significant new use could be allowing workers to use a SNUR substance without wearing a particular respirator. EPA has adopted general regulations identifying the type of activities that could be significant new uses, such as activities related to workplace protection; hazard communication; specific industrial, commercial, and consumer undertakings; disposal; and release to water. 40 C.F.R. Part 721, Subpart B. Each SNUR includes a reference to one or more specific provisions of those general regulations or identifies one or more additional significant new uses.

Thousands of individual SNURs appear in 40 C.F.R. Part 721, Subpart E. (The simple listing alone currently requires 28 printed pages in the Code of Federal Regulations.) A SNUR may apply to more than one chemical substance. For example, one of the SNURs that EPA most recently adopted applies to 35 chemical substances. 40 C.F.R. § 721.11053, 83 Fed. Reg. 37702, 37729-30 (Aug. 1, 2018). At the time the TSCA amendments were enacted, EPA reported that it had already adopted more than 2,800 SNURs. Since enactment it has published direct final rules adopting SNURs covering 268 PMN substances. Walls Decl. ¶ 39.

Under section 5(a)(1)(A)(ii), 15 U.S.C. § 2604(a)(1)(A)(ii), no person may manufacture or process a chemical substance for a significant new use identified in a SNUR for that substance except as provided in section 5(a)(1)(B). Under section 15(1), 15 U.S.C. § 2614(1), it is unlawful for any person to fail or refuse to comply

with that provision. Civil penalties for SNUR violations may be as high as $37,500 per day of violation. Section 16(a)(1), 15 U.S.C. § 2615(a)(1).

Under section 5(a)(1)(B), 15 U.S.C. § 2604(a)(1)(B), an entity wishing to manufacture or process a SNUR substance for a significant new use may request EPA authorization by submitting an application known as a significant new use notice (SNUN) to EPA for its review. The SNUN must describe the proposed conditions of use for engaging in the significant new use. As with a PMN, the content of the SNUN is prescribed by section 5(d) and EPA regulations in 40 C.F.R. Part 720, Subpart C.[7]

Under section 5(a)(3), EPA must review the SNUN and make a risk determination. If it determines that use of the substance as described in the SNUN is "not likely to present an unreasonable risk," under section 5(g), the SNUN submitter may begin to manufacture or process the SNUR substance for the significant new use identified in the SNUN, and EPA must make a public statement of the finding. If EPA determines that use of the substance as described in the SNUN "may present an unreasonable risk," it must issue a section 5(e) order.

[7] EPA's SNUR regulations incorporate the PMN regulations by reference and specify that the form used for PMNs must also be used for SNUNs. 40 C.F.R. § 721.25(a).

EPA's regulations exempt a person who has gone through the SNUN process from having to comply with the SNUR. 40 C.F.R. § 721.45(i). They also exempt a PMN submitter who has received a section 5(e) order for its substance from having to comply with a SNUR for the same substance.

In sum, the SNUR regulations provide a process for EPA review and restrictions that closely mirrors that for PMNs. The application form and the information required are the same; the review process is the same; the risk determinations EPA may make are the same; and the consequences flowing from a risk determination are the same.

A key difference between the two sets of requirements is that the New Chemicals Review Process focuses on the hazards and use conditions described in a PMN, whereas SNURs address changes to previous use conditions (such as those described in a PMN) and new use conditions. Section 5(a)(2), 15 U.S.C. § 2604(a)(2), identifies factors that EPA must consider before adopting a SNUR, with an emphasis on changed conditions. These include, among others, "the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance" and "the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance."

The legislative history of section 5(a)(2) emphasized the importance of changes to previous conditions of use in EPA's decision whether to adopt a SNUR:

> Thus, a significant increase in the projected volume of manufacture or processing for a substance, a significant change in the type or form of human environmental exposure, or a significant increase in the magnitude or duration of human or environmental exposure could be the basis for determining that a use is a significant new use.[8]

Another difference between the New Chemicals Review Process and SNURs is that EPA must adopt a SNUR through rulemaking. To adopt a SNUR, EPA need only determine that a use of a substance is "significant" and "new." "Significant" is a far lower threshold than "presents an unreasonable risk" (the standard under section 6 for rulemaking) or even "may present an unreasonable risk."[9]

Before the 2016 amendments, EPA sometimes adopted a SNUR for a PMN substance for which it had hazard concerns, regardless of whether it had issued a section 5(e) order to the PMN submitter. According to EPA statistics, from 1979 to June 21, 2016, EPA issued 1,729 section 5(e) consent orders, and in almost half those cases (739) EPA followed up with SNURs based on those consent orders

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[8] Conference Report, H.R. Rep. No. 94-1679, at 66 (1976), *reprinted in Legislative History of the Toxic Substances Control Act*, at 670 (1976), and 1976 U.S.C.C.A.N. 4539, 4551.

[9] The legislative history indicates that a "significant" new use is one that "may reasonably be expected to have health or environmental importance." House Report, H.R. Rep. No. 94-1341, at 24 (1976), *reprinted in Legislative History of the Toxic Substances Control Act* (1976), at 431.

(order SNURs). During that same period EPA issued SNURs for 1,457 PMN substances for which it had not issued a section 5(e) order (non-order SNURs). Walls Decl. ¶ 38.

Since the 2016 amendments, EPA has adopted 87 additional order SNURs (covering 213 PMN substances) and 41 non-order SNURs (covering 55 PMN substances). The review periods for all of the substances covered by non-order SNURs ended before enactment of the amendments. Since enactment, EPA has not adopted any non-order SNURs for PMN substances for which it has made a "not likely to present" determination. Walls Decl. ¶ 39. The preambles for most non-order SNURs both before and after enactment describe the respective PMNs and state: "Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk." This statement is similar to, even if not exactly equivalent to, a statement that the PMN substance is "not likely to present an unreasonable risk." Walls Decl. ¶ 39. The draft Framework Document describes a process by which EPA could begin adopting non-order SNURs following a "not likely to present" determination.

EPA must consider adopting a SNUR for any PMN substance for which it has issued a section 5(e) order within 90 days of issuing the order. Section 5(f)(4), 15 U.S.C. § 2604(f)(4). Although there is no requirement for EPA to consider adopting non-order SNURs, EPA has adopted many non-order SNURs even

without a statutory requirement to do so. *See*, *e.g.*, 78 Fed. Reg. 27048, 27050 (May 9, 2013).

B. The Draft Framework Document

The 2016 amendments to TSCA became effective the day of enactment, June 22, 2016. EPA began implementing the changes to section 5 and other TSCA provisions immediately, relying on the statutory provisions themselves. In other words, EPA can implement and has implemented amended section 5 without relying on any version of the draft Framework Document.

TSCA as amended requires EPA to adopt guidance for certain statutory provisions, not including section 5.[10] In addition, the statute requires EPA to adopt "any policies, procedures, and guidance the Administrator determines are necessary to carry out the amendments to this Act" within two years of enactment of the TSCA amendments, and to review and update them no later than five years after enactment, and again every five years thereafter. Section 26(l)(1), (2), 15 U.S.C. § 2625(l)(1), (2). TSCA defines "guidance" to mean "any significant written guidance of general applicability prepared by the Administrator." Section 3(7), 15 U.S.C. § 2602(7). EPA has addressed the initial two-year requirement; it

[10] For example, section 26(l)(5), 15 U.S.C. § 2625(l)(5), directs EPA to adopt guidance on draft risk assessments.

did not designate the draft Framework Document as guidance under the TSCA definition.

EPA held a public meeting to discuss implementation of amended section 5 on December 14, 2016. 81 Fed. Reg. 86713 (Dec. 1, 2016). At that meeting EPA staff made presentations on how EPA anticipated it would implement amended section 5**.** Intervenor SCHF and other stakeholders made oral comments at the meeting. In January 2017, Petitioner, Intervenor SCHF and others submitted written comments. Both the oral and written comments addressed how EPA should interpret and implement the amended section 5. Walls Decl. ¶ 13.

While reviewing the comments it received and considering its significant experience implementing amended section 5, EPA began to revise the approach proposed at the December 2016 meeting. EPA announced a second public meeting and comment period to further discuss how it should implement amended section 5. The notice referred to "EPA's draft New Chemicals Decision-Making Framework." It explained that EPA "plans to utilize the feedback it receives from the public meeting and comments received to improve policy and processes relating to the review of new chemicals under TSCA," and that "[i]nformation obtained during this meeting and collected in the docket will be considered as the Agency works to increase efficiency in its review process under TSCA."

82 Fed. Reg. 51415, 51416 (Nov. 6, 2017). The next day EPA posted the draft Framework Document on its website. Walls Decl. ¶¶ 14-15.

The five-page draft Framework Document followed the December 2016 approach in part and differed in part by indicating the following:

- 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.

- 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.

Draft Framework Document at 2.

At the December 6, 2017 public meeting, EPA discussed the draft Framework Document and received oral comments on it. Petitioner and Intervenor SCHF made oral comments, as did others. In January 2018, Petitioner and Intervenor SCHF submitted written comments, as did others. Walls Decl. ¶ 16. EPA is considering those comments. Declaration of Jeffrey Morris (Morris Decl.) ¶ 7.

EPA has not relied on the draft Framework Document for any decisions under amended section 5, at least with respect to the aspects contested by Petitioner. Walls Decl. ¶¶ 17-19.

SUMMARY OF THE ARGUMENT

Petitioner and Intervenor SCHF have not demonstrated standing. Even were they able to do so, they challenge a draft, non-binding policy statement that is not a legislative rule subject to the Administrative Procedure Act (APA). Moreover, the draft policy statement is not final, has not been implemented, and is partway through a notice and comment process. As to the merits, the draft Framework Document is consistent with TSCA. If EPA implements it, doing so would protect health and the environment.

Petitioner and Intervenor SCHF have failed to meet jurisdictional requirements. They lack standing, as their members are not affected by the draft Framework Document in any way. Petitioner and Intervenor SCHF would not be prejudiced by dismissal of the petition for review, as they could challenge individual non-order SNURs or "not likely to present" determinations (if they were able to demonstrate standing to do so).

The APA does not apply to the draft Framework Document. Its requirement for notice-and-comment rulemaking applies only to legislative rules, and the draft Framework Document is not a legislative rule. In any case, EPA is in the midst of notice and comment on the draft. Petitioner and Intervenor SCHF provided comments on the draft Framework Document and EPA has stated that it is considering those and other public comments.

As EPA's brief explains, the draft Framework Document provides one option for EPA's approach to implementing section 5. That option is entirely consistent with section 5 as amended.

Petitioner and Intervenor SCHF distort the requirement that EPA consider the conditions of use in making a risk determination, seeking to dictate what EPA's risk determination must be. If a condition of use is reasonably foreseen and of concern, they argue, EPA must make a "may present an unreasonable risk" determination and issue a section 5(e) order. However, EPA could consider reasonably foreseen conditions of use to be of concern, and still determine that they do not mean that the PMN substance "may present an unreasonable risk." As part of its determination, EPA may consider that a statutorily-provided SNUR would change the conditions of use by effectively restricting both the PMN submitter and potential future manufacturers and processors.

Petitioner's argument that EPA must issue a section 5(e) order to restrict potential future manufacturers and processors is inconsistent with section 5(e) itself. Section 5(e) allows EPA to issue an order imposing restrictions on the PMN submitter "to the extent necessary to protect against an unreasonable risk." Such orders can only restrict the PMN submitter itself; they cannot provide any protection at all from any risks presented by potential future PMN submitters and

processors. Thus, such orders would not be "necessary" because they would be completely ineffective for the purpose identified by Petitioner.

EPA may also make a "not likely to present" determination based on an amended PMN in appropriate circumstances, notwithstanding the possibility that future manufacturers and processors, or the PMN submitter itself, may not follow the exposure controls in a PMN. EPA may reasonably make a "not likely to present" determination based, in part, on the existence of a SNUR or its consideration of adopting a SNUR in the future, knowing that a SNUR would be effective in ensuring that appropriate restrictions would be implemented. Amended section 5 gives EPA the authority to make risk determinations, and Petitioner and Intervenor SCHF are not entitled to substitute their judgment for EPA's or to alter the statutory process.

The draft Framework Document would, if implemented, fully protect health and the environment. SNURs, including non-order SNURs, are well designed to bar any person from engaging in practices for which EPA has concerns (referred to as significant new uses). The only way for a person to engage in those practices would be to submit to EPA for review a detailed application (SNUN), and for EPA to make a risk determination, and identify restrictions in light of the risk determination.

Petitioner and Intervenor SCHF made a facial challenge to the entirety of the draft Framework Document, yet they have not demonstrated that the draft as a whole is illegal. Because numerous matters not contested by Petitioner and Intervenor SCHF could be properly addressed consistent with the draft Framework Document, their facial challenge must fail.

STANDARD OF REVIEW

Petitioner bears the burden to show: (1) that it has standing to bring the petition; (2) that this Court has subject matter jurisdiction to review the petition; and (3) that the petition is ripe for this Court's review. *LaFleur v. Whitman*, 300 F.3d 256, 268 (2d Cir. 2002) (standing); *Kokkonen v. Guardian Life Ins. Co. of America*, 511 U.S. 375, 377 (1994) (subject matter jurisdiction); *Sunrise Detox V, LLC v. City of White Plains*, 769 F.3d 118, 121 (2d Cir. 2014) (ripeness). This Court also has an independent obligation to confirm that standing exists and that the Court has jurisdiction. *Green Island Power Authority v. F.E.R.C.*, 577 F.3d 148, 160 (2d Cir. 2009) (appellate court has "an independent obligation to conduct [its] own standing inquiry") (internal punctuation removed); *Dean v. Blumenthal*, 577 F.3d 60, 64 (2d Cir. 2009) (appellate court has "an independent obligation" to evaluate subject matter jurisdiction).

Even if the draft Framework Document were reviewable, Petitioner must also overcome this Court's presumption that agency actions are valid. *Sierra Club*

v. U.S. Army Corps of Engineers, 772 F.2d 1043, 1051 (2d Cir. 1985) ("Courts must defer to the action taken by the agency, which is presumed to be valid.") (citing *Citizens to Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 419 (1971)). Unless an agency action is arbitrary or capricious, or otherwise not in accordance with the law, it must be upheld. 15 U.S.C. § 2618(c)(1)(A), (B); *National Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1036 (D.C. Cir. 2012) (TSCA authorizes judicial review under APA standards). Under this deferential standard, this Court "may not substitute its judgment for that of the agency," particularly where – as here – the action "is propelled by the agency's scientific expertise." *Henley v. Food and Drug Admin.*, 77 F.3d 616, 620 (2d Cir. 1996) (internal punctuation omitted) (citing *Overton Park*, 401 U.S. at 416; *Baltimore Gas & Elec. Co. v. Natural Resources Defense Council, Inc.*, 462 U.S. 87, 103 (1983)). Therefore, so long as the agency "articulate[s] a satisfactory explanation for its action," the action must be upheld. *Id.*

ARGUMENT

I. PETITIONER HAS FAILED TO ESTABLISH THAT IT HAS STANDING

A party seeking associational standing has the burden to establish, among other things, that at least one of its members would meet the three irreducible Article III standing requirements. *Lujan v. Defenders of Wildlife*, 504 U.S. 555, 563 (1992). First, the party must show an "injury-in-fact" that is both (a) "concrete

and particularized" and (b) "actual or imminent, not conjectural or hypothetical." *Id*. at 560 (internal citations omitted). Second, the party must demonstrate a causal connection between the alleged injury and the defendants' conduct. *Id*. Third, the party must demonstrate that it is "likely, as opposed to merely speculative that the injury would be redressed by a favorable decision." *Id*. at 561 (internal citation and punctuation omitted). Petitioner fails to meet any of these burdens.

A. Petitioner Does Not Demonstrate a Cognizable Injury-in-Fact

Even if Petitioner's merits arguments were correct – which they are not – Petitioner has not met its burden to show an injury-in-fact. When a party seeks to establish a pending injury, it must show that the alleged injury is "imminent" and "*certainly* impending." *Lujan*, 504 U.S. at 560, 564 n.2 (emphasis added). The Supreme Court has held that showings of "*possible* future injury" or "*realistic* threat" do not meet this high bar. *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 409 (2013) ("*possible* future injury" showing not sufficient) (emphasis added); *Summers v. Earth Island Institute*, 555 U.S. 488, 500 (2009) ("*realistic* threat" showing not sufficient) (emphasis in original).

As EPA notes, under Supreme Court precedent, a legal instrument that "*authorizes* – but does not *mandate* or *direct*" relevant conduct establishes that a party's allegations of harm are "necessarily conjectural" and not imminent or certainly impending. *Clapper*, 568 U.S. at 412 (emphasis in original); *see also*

EPA Brief at 22. This is fully consistent with a line of appellate cases, including in this Circuit, holding that a party's alleged harm is not "actual or imminent" where an intermediate step would be necessary before any harm were to occur. *Nat. Res. Def. Council v. FDA*, 710 F.3d 71, 85-86 (2d Cir. 2013); *Deutsche Bank National Trust Co. v. FDIC*, 717 F.3d 189 (D.C. Cir. 2013); *Sierra Club v. EPA*, 873 F.3d 946, 950 (D.C. Cir. 2017).

These cases are precisely on point. Petitioner alleges (incorrectly) that the draft Framework Document would authorize certain actions with respect to individual chemicals. But Petitioner lacks even a colorable argument that the document "mandates" or "directs" any conduct whatsoever. The document, which EPA explicitly described as a "draft" in its Federal Register notice, 82 Fed. Reg. 51415 (Nov. 6, 2017), merely articulates one possible interpretation of the 2016 amendments. It lays out EPA's non-binding "inten[t]" and "expect[ation]" for certain aspects of its new chemicals program. By the document's own terms, and EPA's statements to this Court, the document does not bind the Agency. EPA Brief at 17. For this reason alone, Petitioner cannot establish a cognizable injury-in-fact.

Additionally, as EPA notes in its brief, Petitioner's alleged injuries would not occur but for a series of speculative, future steps. EPA Brief at 23. Namely, EPA would first have to: (1) choose to rigidly adhere to the draft Framework

Document; (2) obtain a PMN from a regulated entity; and (3) conclude that the relevant substance did not pose a significant risk due to a significant new use rule. Even if Petitioner were able to establish that such a chain of events were "possible" or "realistic," Petitioner would still lack standing under Supreme Court precedent. EPA's testimony before this Court establishes that such a chain of events has not happened since enactment of the 2016 amendments. Morris Decl. ¶ 10. Petitioner therefore cannot establish that these events are "imminent" or "certainly occurring." For this independent reason, Petitioner cannot establish a cognizable injury-in-fact.

B. Petitioner Does Not Establish a Causal Connection Between the Alleged Injury and the Alleged Harm

Petitioner also fails to establish a causal connection between the draft Framework Document and the future injury it predicts. Article III requires parties seeking standing to demonstrate that the alleged injury "is fairly traceable to the challenged action." *Friends of the Earth, Inc. v. Laidlaw Environmental Services (TOC), Inc.*, 528 U.S. 167, 180 (2000). Petitioner cannot make this showing for many of the same reasons it cannot show injury-in-fact. As noted *supra*, Petitioner's argument relies on a lengthy and unlikely chain of conjecture – a series of events that have not occurred in the two years since TSCA was amended. Morris Decl. ¶ 10. This is insufficient to support Petitioner's standing arguments. *Florida Audubon Soc. v. Bentsen*, 94 F.3d 658, 666 (D.C. Cir. 1996) (en banc)

(appellants that "premise[d] their claims of particularized injury and causation on a lengthy chain of conjecture" lacked standing).

C. Petitioner's Alleged Injury Would Not be Redressed by the Relief It Seeks

Finally, for a party to have standing, "it must be likely, as opposed to merely speculative, that the injury will be redressed by a favorable decision." *Lujan*, 504 U.S. at 560-61. Petitioner makes no such showing. As noted *supra*, the Framework Document does not bind EPA to a particular course of conduct. Rather, EPA's PMN decisions apply the statute, which a favorable decision for Petitioner would not change. *National Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 933 (D.C. Cir. 2004) (party failed to establish that revocation of policy interpretations would redress alleged harms where "legal regime" would remain in place). Further, the extent to which EPA applies this draft non-binding policy statement now, or will do so in the future, is open to speculation. For example, the document could be amended, set aside, or replaced as EPA gains more experience evaluating chemicals under the 2016 amendments and continues to consider public comments. If that were to occur, this Court's vacatur of the Framework Document would be irrelevant. Thus, Petitioner cannot establish redressability, and lacks standing.

II. PETITIONER FAILS TO DEMONSTRATE SUBJECT MATTER JURISDICTION

Petitioner fails to carry its burden to establish that this Court has subject matter jurisdiction to decide its claims. *Kokkonen v. Guardian Life Ins. Co. of Am.*, 511 U.S. 375, 377 (1994) ("It is to be presumed that a cause lies outside [a federal court's] limited jurisdiction, and the burden of establishing the contrary rests upon the party asserting jurisdiction.") (citations omitted). As Petitioner admits, this Court's jurisdiction under TSCA § 2618(a)(1)(A) is limited to "final rules." Pet. Br. at 4. The Supreme Court has held that two conditions must be met for an agency action to be considered final: (1) the action must mark the end of the agency's decision making process and "must not be of a merely tentative or interlocutory nature"; and (2) the action "must be one by which rights or obligations have been determined or from which legal consequences will flow." *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997). Petitioner does not and cannot establish that either condition is met. By its own terms, the document is a draft. It is partway through a notice and comment process without any final decision. It has not been implemented. It does not determine binding responsibilities. It does not outline "rights or obligations." The Court therefore lacks subject matter jurisdiction over this matter.

A. The Draft Non-Binding Policy Statement Is "Merely Tentative" and Does Not Mark the End of EPA's Process

The draft non-binding policy statement is – in word and in substance – tentative and interlocutory. EPA provided notice and opportunity for the public to comment and is in the process of considering those comments. EPA Brief at 13. Both the document itself and the Federal Register notice seeking comment make plain that the document is an evolving draft. Draft Framework Document at 1 (stating in introductory language that the document is "expect[ed] to evolve"); 82 Fed. Reg. 51415 (Nov. 6, 2017) (labeling the Framework Document as a "draft" and stating that EPA "plans to utilize the feedback it receives … to improve policy and processes").

The document's interlocutory nature is manifest in Petitioner's failure to allege any specific instances since TSCA amendment – whether before or after the draft non-binding policy statement was issued – where EPA's consideration of reasonably foreseen uses was narrower than required by the statute. EPA has not issued any SNURs in the way contemplated by the draft Framework Document since the document was released and the few "not likely to present an unreasonable risk" determinations EPA has made did not consider a SNUR as a factor in the determination. Morris Decl. ¶ 10; Walls Decl. ¶¶ 18-19, 39. Because the Framework Document is an evolving draft, both by its own terms and in effect, the document is not final and this Court lacks subject matter jurisdiction.

B. The Draft Non-Binding Policy Statement Does Not Establish Legal Obligations

If an agency document does not have legal effect – that is, if it does not "impose an obligation," "den[y] a right," or "fi[x] some legal relationship," federal courts lack subject matter jurisdiction to review it. *Paskar v. U.S. Dep't of Transp.*, 714 F.3d 90, 96 (2d Cir. 2013) (discussing the second condition in *Bennett v. Spear*, 520 U.S. 154, 177-178). Courts reviewing this second *Bennett* condition consider its "substantial practical impact." *Salazar v. King*, 822 F.3d 61, 82 (2d Cir. 2016) (quoting *Paskar*, 714 F.3d at 97-98). Petitioner can point to no term in the draft Framework Document that binds EPA or any other entity.

To the contrary, the document itself articulates an interim alternative that EPA "intends" to implement, but "expects to evolve." Draft Framework Document at 1. The document thus expressly declines to bind EPA to any particular interpretation, or to any specific course of action. Furthermore, Petitioner fails to establish that the draft Framework Document has had any "substantial practical impact," let alone the impact Petitioner fears. *See supra* at p. 22. The document merely describes certain possible interpretations – draft interpretations – of section 5. For this independent reason, this Court lacks subject matter jurisdiction over Petitioner's claims.

C. Petitioner's Claims are Unripe and Petitioner Would Not Be Prejudiced by Dismissal

This Court should decline to consider Petitioner's claims because they are unripe. The ripeness doctrine seeks to prevent, among other things, courts "entangling themselves in abstract disagreements over administrative policies … until an administrative decision has been formalized and its effects felt in a concrete way by the challenging parties." *Entergy Nuclear Vermont Yankee, LLC v. Shumlin*, 733 F.3d 393, 429 (2d Cir. 2013) (quoting *Abbott Labs v. Gardner*, 387 U.S. 136, 148-49 (1967)). The doctrine is "drawn both from Article III limitations on judicial power and from prudential reasons for refusing to exercise jurisdiction." *National Park Hospitality Ass'n v. Dep't of Interior*, 538 U.S. 803, 808 (2003). In evaluating ripeness, courts must consider "the hardship to the parties of withholding court consideration." *Sharkey v. Quarantillo*, 541 F.3d 75, 89 (2d Cir. 2008). If a challenger cannot show that an agency action caused it concrete hardship, the challenge is unripe. *Toilet Goods Ass'n., Inc. v. Gardner*, 387 U.S. 158, 161-62 (2003) (holding a challenge to agency action unripe for lack of a showing of hardship). Petitioner cannot make such a showing, and its challenge should be dismissed.

The petition represents precisely the type of entanglement over "abstract disagreements" the ripeness doctrine seeks to avoid. The draft Framework Document presents a non-binding draft interpretation of certain TSCA provisions.

Petitioner points to no instance of the interpretation being applied to any specific substances, EPA has stated to the Court that it has not so applied the draft interpretation, and it is far from clear whether the interpretation will ever be applied in the future. Petitioner therefore utterly fails to show that the draft Framework Document has had any effects at all, let alone effects Petitioner has "felt in a concrete way."

Petitioner also cannot show any hardship or prejudice that would stem from dismissal. EPA concedes that Petitioner – or indeed any party – could challenge EPA actions pertaining to specific chemicals.[11] EPA Brief at 42-43. This includes an EPA determination that a substance is "not likely to present an unreasonable risk." *Id*. (citing 15 U.S.C. § 2604(a)(3) and 5 U.S.C. § 704). Additionally, significant new use rules may be challenged by petition directly to courts of appeal. 15 U.S.C. § 2618(a)(1)(A). Rather than enmeshing itself in the instant ongoing and fluid discussion of non-binding statutory interpretation, the Court should await a ripe presentation of a specific statutory interpretation, as applied.

III. THE NON-BINDING POLICY STATEMENT IS NOT SUBJECT TO NOTICE AND COMMENT REQUIREMENTS

The draft non-binding policy statement imposed no rights or obligations on any party; it merely informed the public of certain EPA statutory interpretations at

[11] Any such challenger must, of course, establish that it has standing. *Lujan v. Defs. of Wildlife*, 504 U.S. 555 (1992).

the time. Although APA notice and comment procedures were not required, EPA held public meetings, solicited and received public comments – both oral and written – and is in the process of considering such comments. Morris Decl. ¶ 7. Petitioner's argument that EPA was required, but failed, to follow notice and comment procedures is therefore wrong on all counts. Pet. Br.at 41-49.

Statements of statutory interpretation need not go through notice and comment. *Perez v. Mortgage Bankers Ass'n*, 135 S. Ct. 1199, 1204 (2015) (statements "issued by an agency to advise the public of the agency's construction of the statutes … which it administers" are not subject to notice and comment requirements); *White v. Shalala*, 7 F.3d 296, 303 (2d Cir. 1993) (an agency statement "clarify[ing] an existing statute" is not subject to notice and comment requirements); *New York City Employees' Retirement System v. S.E.C.*, 45 F.3d 7, 12 (2d Cir. 1995) (same); *Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710, 716 (D.C. Cir. 2015) (a guidance document, whether regarded as a policy statement or interpretive rule, does not require notice and comment).

The central question is whether the relevant agency document is "legislative" or "interpretive" in nature. *Perez*, 135 S. Ct. at 1203-04.[12] Only the

[12] APA case law on this subject focuses on the distinction between "interpretive rules" and "legislative rules." *See, e.g., Perez*, 135 S. Ct. at 1203-04. The relevant APA definition of "rule" is broad enough to cover a variety of agency documents, even if they are not published in the Federal Register and create no legal rights or obligations. 5 U.S.C. § 551(4) (defining rule to include "the whole or a part of an

former are required to go through notice and comment. *Id*. The inquiry shares common elements with the subject matter jurisdiction and ripeness issues discussed above: legislative documents are those that "create new law, rights, or duties," while interpretive documents merely "clarify an existing statute or regulation." *White*, 7 F.3d at 303. As demonstrated *supra*, the draft Framework Document – a draft, non-binding policy statement – merely posits an interpretation of TSCA provisions without imposing rights or duties on EPA or any other party.[13] It is therefore interpretive, and need not be subject to formal notice and comment rulemaking.

Petitioner's arguments that any differences between the draft Framework Document and EPA's prior interpretations triggered notice and comment requirements are equally unavailing. It is well-established that a change from one statutory interpretation to another does not require notice and comment. *See, e.g.*, *Perez*, 135 S. Ct. at 1206 ("Because an agency is not required to use notice-and-

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agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency"). For example, in *New York City Employees' Retirement System*, this Court held that an agency letter was a legislative "rule" not subject to notice and comment requirements. 45 F.3d at 14.

[13] For purposes of evaluating the Petition, it is of no moment whether the draft Framework Document meets the TSCA definition of a guidance document. 15 U.S.C. § 2602(7) (defining guidance as "any significant written guidance of general applicability prepared by the Administrator"). It is the APA, not TSCA, that Petitioner alleges imposed notice and comment obligations on EPA. Pet. Br. at 41.

comment procedures to issue an initial interpretive rule, it is also not required to use those procedures when it amends or repeals that interpretive rule."); *White*, 7 F.3d at 304 ("[A]n interpretive rule changing an agency's interpretation of a statute is not magically transformed into a legislative rule").

In choosing to provide additional opportunities for public input, EPA opted to go beyond its obligations.[14] This choice reflected an admirable intent for EPA to consider the positions of a wide variety of stakeholders before even releasing draft non-binding interpretations of TSCA.

The process began with EPA announcing a public meeting and soliciting written comments on various aspects of its new chemicals review program, including PMNs. 81 Fed. Reg. 86713 (Dec. 1, 2016) (stating that the meeting would cover "the New Chemicals Review Program, including submittal of pre-manufacture notices … under section 5 of the law."). EPA explained that "[i]nformation obtained during these meetings will be considered as the Agency works to implement the new requirements and increase efficiency in its review process under TSCA." *Id*. at 86713. As noted above, EPA solicited another round of comment on this document in 2017. 82 Fed. Reg. 51415 (Nov. 6, 2017).

[14] EPA's choice to go beyond its obligations does not affect the legislative/interpretive analysis. *Sierra Club v. EPA*, 873 F.3d 946, 952 (D.C. Cir. 2017) ("an agency's decision to embrace additional process cannot convert a guidance document into a legislative rule").

Thus, even if the draft Framework Document did trigger notice and comment obligations, under Petitioner's theory of the case, EPA has satisfied them. The APA prescribes a three-step process for notice and comment rulemaking. 5 U.S.C. § 553. "First, the agency must issue a general notice of proposed rulemaking, ordinarily by publication in the Federal Register." *Perez*, 135 S. Ct. at 1203 (citing 5 U.S.C. § 553(b)) (internal punctuation omitted). Second, the agency must "give interested persons an opportunity to participate in the rule making through submission of written data, views, or arguments." *Id*. (citing 5 U.S.C. § 553(c)). Third, when the final rule is published, it must be accompanied by "a concise statement of [its] basis and purpose." *Id*. Each of the steps was satisfied in this case under Petitioner's theory of the case. EPA's December 1, 2016 Federal Register announcement and invitation to submit written comments – an invitation Intervenor SCHF accepted – satisfied the first two steps. Under Petitioner's theory of the case, EPA's November 6, 2017 Federal Register notice and the introductory language of the draft Framework Document would itself have satisfied the third.[15]

[15] Petitioner's theory is undermined by EPA's statement to the Court that it is in the process of reviewing the public comments. *See* Morris Decl. ¶ 7.

IV. EVEN IF THE DRAFT FRAMEWORK DOCUMENT WERE REVIEWABLE, IT IS CONSISTENT WITH TSCA

Petitioner and Intervenor SCHF misapprehend both the draft Framework Document and TSCA. Their multiple arguments rely on those misapprehensions and should be rejected. They make a fundamental error by failing to read section 5 as a whole, including its SNUR provisions. As explained below, the draft Framework Document is fully consistent with TSCA, and the instant facial challenge to the document fails.

A. EPA May Reasonably Make a "Not Likely to Present" Determination Based on the Totality of the Circumstances

Petitioner and Intervenor SCHF assert that whenever EPA has "concerns" attributable to reasonably foreseeable conditions of use of potential future manufacturers and processors, it must make a "may present an unreasonable risk" determination and issue a section 5(e) order to the PMN submitter. This grossly misreads section 5.

Their assertion relies on the following statement on page 2 of the draft Framework Document (Pet. Br. at 19):

> 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.

This statement does not mean, as Petitioner claims, that "EPA limits its review of a new chemical substance to the manufacturer's intended conditions of use" or that EPA will "use a significant new use rule to defer its review of *all* of the conditions of use." Pet. Br. at 30-31. Nor does it mean that the draft Framework Document only provides that intended conditions of use need to be considered. Intv. Br. at 41.

By its terms, the draft Framework Document anticipates that in reviewing a PMN EPA may identify "concerns" with "reasonably foreseen conditions of use" associated with potential future manufacturers and processors or potential changes to the PMN submitter's conditions of use. Draft Framework Document at 2. If EPA identifies such concerns, it will then "assess whether those concerns can be addressed" through a SNUR. *Id.* The result of that assessment will be one factor among others that it weighs in making a risk determination. The draft Framework Document makes clear that EPA would not ignore concerns associated with "reasonably foreseen" conditions of use – it would consider them, along with other factors, in its risk determination. *Id.*

"Concerns," however, do not inevitably lead to a "may present" determination. Some concerns may give rise to a "may present" determination,

while others do not.[16] Section 5(a)(3) directs EPA to "determine" the risk of a PMN substance. Such a determination is an exercise of expert judgment by EPA. That judgment may, for instance, reasonably consider a SNUR or the potential for a SNUR to address concerns. EPA routinely evaluates concerns in making risk determinations under section 5. The simple fact that a concern exists does not in and of itself dictate the outcome of such determinations. EPA evaluates the nature of the concern as well as the full context in which it exists in making its risk determinations. Walls Decl. ¶¶ 20-21.

Petitioner and Intervenor SCHF argue that the draft Framework Document substitutes a SNUR for a section 5(e) order. Pet. Br. at 30-32. However, section 5(a)(3) mandates that EPA issue a section 5(e) order *only* where it has made a "may present" determination. The draft Framework Document contemplates that in appropriate circumstances, despite having "concerns," EPA need not make a "may present" determination after considering all relevant information. For example, it might make a "not likely to present" determination based, in part, on the existence of a SNUR or its consideration of adopting a SNUR in the future, where the SNUR would ensure that appropriate restrictions would be implemented. *See* discussion of SNUR timing, *infra* at 50-55.

[16] EPA routinely differentiates among concerns, for example, classifying some as high, moderate, or low. Walls Decl. ¶¶ 20-21.

Intervenor SCHF asserts that "EPA cannot avoid such orders if it is 'reasonably foreseen' that the PMN submitter or other manufacturers and processors will fail to comply with the voluntary control measures in the amended PMN … ." Intv. Br. at 41-42. This is a clear instance of Intervenor SCHF inappropriately seeking either to substitute its judgment for that of EPA with respect to risk determinations, or to skip the risk determination step altogether. Intervenor SCHF also seeks to impose its judgment that the action triggered by a "may present" determination, a section 5(e) order, is mandatory in every case where EPA has "concerns," regardless of EPA's evaluation of those concerns.

Taking the statute as a whole, EPA can and should consider the existence or likelihood of a SNUR in evaluating a PMN when making a risk determination "under the conditions of use." A SNUR could effectively limit potential future manufacturers' and processors' conditions of use as well as those of the PMN submitter. A SNUR that is already in effect would obviously impact those conditions of use. So too would a SNUR that is not in effect but that EPA plans to adopt. The existence or potential availability of a SNUR to restrict their conditions of use should be considered as part of the risk determination.

Another factor that EPA may reasonably consider in assessing any concerns as part of its risk determination is the extent to which a section 5(e) order issued to the PMN submitter would address concerns about potential future manufacturers

and processors. If EPA makes a "may present" determination for a PMN substance, it must issue a section 5(e) order to the PMN submitter – but not to anyone else. EPA recognizes, as does Intervenor SCHF, that potential future manufacturers and processors "are not bound by a section 5(e) order, which only applies to the PMN submitter." Intv. Br. at 8 n.8.[17] This is an important consideration. Petitioner claims that under section 5, EPA has no choice but to issue a section 5(e) order to a PMN submitter even when EPA has no concerns about the PMN submitter's conditions of use but does have concerns about persons who would be unaffected by that order. That defies common sense and is not mandated by the statute. Petitioner's position would cause EPA to violate section 2(c), 15 U.S.C. § 2601(c), which directs EPA to "carry out this chapter in a reasonable and prudent manner."

Instead, when EPA has concerns but determines that they do not mean that the substance "may present an unreasonable risk," a broadly applicable SNUR may be appropriate while a section 5(e) order to the PMN submitter alone would have no effect on those concerns.

[17] *See* 55 Fed. Reg. 17376, 17377 (Apr. 24, 1990) ("Section 5(e) orders apply only to PMN submitters."). This Federal Register notice was for the first direct final SNURs adopted by EPA. EPA has repeatedly referenced it in preambles to subsequent direct final SNURs. *See, e.g.*, 82 Fed. Reg. 48637, 48638 (Oct.19, 2017).

Section 5(e)'s language endorses this reasoning. A section 5(e) order must impose restrictions on the PMN submitter "to the extent necessary to protect against an unreasonable risk." Section 5(e), 15 U.S.C. § 2604(e). An order that applies only to the PMN submitter would not protect against concerns related to potential future manufacturers and processors. Such an order cannot be considered "necessary."

B. EPA May Reasonably Make a "Not Likely to Present" Determination Based in Part on Conditions of Use in an Amended PMN

Intervenor SCHF objects to the following statement from the draft Framework Document at page 2:

> 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.

It argues that EPA cannot rely on "unenforceable commitments" in "amended PMNs" in making a "not likely to present" determination. Intv. Br. at 39. Intervenor SCHF does not object to EPA basing a "not likely to present" determination on information in the PMN as originally submitted, but it is somehow concerned with EPA considering amended information. It ignores that the amended PMN is subject to the same certification under penalty of perjury as the original PMN.

Under section 5(a)(3), EPA must make its risk determinations based in part on the conditions of use, a statutory term that includes, among others, the intended conditions of use. Under section 5(d) and EPA regulations, 40 C.F.R. Part 720, Subpart C, these must be described in the PMN. If the intended conditions of use (as indicated in a PMN or an amended PMN) reflect controls that satisfy EPA concerns, that fact must be weighed by EPA in making its risk determination, along with other information. Section 5(a)(3) requires EPA to "review such notice and determine" the risk level. In other words, EPA cannot ignore the information in the PMN. Further, section 26(k), 15 U.S.C. § 2625(k), provides that in carrying out section 5, EPA "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." Certainly, information in an amended PMN is "reasonably available" to EPA, and EPA must therefore take it into consideration as it makes its risk determination.

EPA must also consider reasonably foreseen conditions of use. The draft Framework Document does not preclude this. Petitioner asserts that in the absence of a section 5(e) order, it is reasonably foreseeable that the PMN submitter might not implement the exposure controls in the amended PMN. In fact, PMN submitters do implement the exposure controls in their PMNs, so long as circumstances are the same. Walls Decl. ¶¶ 23-25. This is attributable in part to

the fact that every PMN submitter must have an Authorized Official certify on page 2 of the PMN form "to the best of [his or her] knowledge and belief" that "all information provided in this notice is complete and truthful as of the date of submission." Walls Decl. ¶ 24. The PMN form accompanies that statement with the following admonition:

> The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 USC 1001.

Id. PMN submitters are well aware that if they make the PMN certification, but then do not implement the exposure controls identified in the PMN (or amended PMN), they risk civil enforcement or criminal liability. *Id*.

EPA can and, in appropriate circumstances, must consider the possibility that at some point a PMN submitter might not implement all the exposure controls in its amended PMN. In making its risk determination, EPA must weigh that factor, along with other information. Intervenor SCHF would regard that factor as determinative, mandating that EPA make a "may present" determination in every situation. However, that is not consistent with the statute.

When considering reasonably foreseen (potential, not actual) conditions of use in the course of making a risk determination, EPA must also consider the potential for mandatory controls on those conditions of use, as such controls would, if adopted, become part of the conditions of use. EPA may impose such

controls on the PMN submitter either through a section 5(e) order or on the PMN submitter and others through a SNUR. Consistent with the statutory requirements, the draft Framework Document directs EPA to assess the effectiveness of a SNUR in addressing EPA's concerns. Draft Framework Document at 2.

Petitioner asserts that SNURs "are not a means by which EPA can require a manufacturer to follow its outlined conditions of use." Pet. Br. at 40. It misreads a provision in EPA's regulation on expedited adoption of non-order SNURs. *See* 40 C.F.R. § 721.170(c)(2). That regulation states that "EPA may designate as a significant new use only those activities that (i) are different from those described in the premanufacture notice for the substance, including any amendments, deletions, and additions of activities to the premanufacture notice …." This language allows EPA to designate the failure to implement controls described in the PMN or amended PMN as a significant new use, because that would involve activities that "are different from" those described in the PMN or amended PMN. Having done so, EPA could effectively prohibit the PMN submitter from engaging in that significant new use, *i.e.*, failing to implement those controls, unless and until EPA reviewed a SNUN submitted by the PMN submitter and either issued a section 5(e) order imposing restrictions or made a "not likely to present" determination.

Petitioner misapprehends the statutory role of SNURs. That role includes, where appropriate, effectively addressing health and environmental concerns that may arise as a result of changes to the conditions of use described in a PMN. Those changes may result from the PMN submitter changing its conditions of use or from other parties manufacturing or processing the PMN substance. *See* pp. 47-48, *infra*.

Accordingly, in making its risk determination, EPA must consider the exposure controls in an amended PMN, and it may consider the effectiveness of a SNUR to enforce use of those controls by the PMN submitter and others. After considering those factors and others, EPA may make a "may present" determination, in which case it must issue a section 5(e) order to the PMN submitter. Alternatively, it may judge that, taking all relevant available information into account, a "not likely to present" determination is appropriate. Petitioner and Intervenor SCHF may not pre-judge and dictate to EPA the outcome of the Agency's risk determination.

C. Petitioner and Intervenor SCHF Would Cause EPA to Violate TSCA

Petitioner and Intervenor SCHF would require EPA to issue section 5(e) orders even where the orders would not protect health or the environment or where a SNUR would be more useful and appropriate. This incorrect interpretation would inevitably result in significant delays in the statutorily mandated 90-day

review period, which in turn would lead EPA to violate both section 5(a)(3) and section 2(b)(3).

Section 5(a)(3) mandates that EPA complete its PMN reviews within the applicable review period. Section 5(i)(3) defines "applicable review period" to mean 90 days from receipt of the PMN, unless EPA formally extends the review period under section 5(c) for a maximum of another 90 days, in which case EPA must publish a Federal Register notice to that effect. Section 5(a)(4)(A), 15 U.S.C. § 2604(a)(4)(A), provides a sanction on EPA for missing that deadline: EPA must refund the fee charged for submitting a PMN if it fails to complete its review before the end of the applicable review period.

The legislative history of the TSCA amendments emphasized the importance of EPA meeting that deadline.[18] Section 5(g) authorizes EPA to make a "not likely to present" determination in less than 90 days, and the legislative history tied this

[18] For example, the Senate Report advises, "consistent with current law the Agency should continue the practice of completing new chemical reviews within 90 days." Sen. Rep. No. 114-67, at 15 (2015). Senator Vitter emphasized that the legislation protected innovation in several ways, but through the 90-day deadline first of all: "First, the compromise retains the 90-day review period for EPA to make a risk-based decision on a new chemical, without consideration of costs or other non-risk factors." 162 Cong. Rec. S3520 (daily ed. June 7, 2016).

to avoiding unnecessary delay to the PMN submitter in bringing its substance to market[19] and thereby facilitating innovation.

The proposed process of Petitioner and Intervenor SCHF could cause EPA in many cases to fail to complete its review within 90 days. It would require EPA to issue section 5(e) orders even where they would be ineffective to address the reasonably foreseen conditions of use of potential future manufacturers and processors. The time needed to prepare such consent orders would very likely take months. The experience of PMN submitters is that their negotiations with EPA over the provisions of section 5(e) orders often take several months or longer. EPA may obtain the PMN submitter's agreement to suspend the running of the review period. Nevertheless, whenever a section 5(e) order is involved, the review period typically takes many multiples of 90 days. Walls Decl. ¶ 26. Such unnecessary delays would violate section 5(a)(3).

Section 2(b)(3), 15 U.S.C. § 2601(b)(3), directs EPA to exercise its TSCA authority "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." The legislative history acknowledged the importance of the New Chemical Review Process not

[19] "This provision ensures that chemicals considered not likely to pose an unreasonable risk are not delayed in getting to market." *Id.* (remarks of Senator Vitter).

unnecessarily burdening innovation.[20] Delays by EPA in making its risk determinations do create unnecessary barriers to innovation by postponing the arrival of vital new chemical substances on the market. Unnecessary section 5(e) orders would cause further delays, and this would create further unnecessary barriers, leading EPA to violate section 2(b)(3).

V. THE DRAFT FRAMEWORK DOCUMENT WOULD PROTECT HEALTH AND THE ENVIRONMENT

Petitioner and Intervenor SCHF attack the draft Framework Document by disparaging statutorily-provided SNURs. These attacks reflect a misunderstanding of how section 5, read as a whole, works. Decades of EPA experience show that the draft Framework Document would protect health and the environment.

[20] For example, the Senate Report said, "The Committee intends the amendments to section 5 to ensure that EPA conducts an appropriate review of the potential health and environmental effects of new chemicals, while supporting the ability of manufacturers and processors to innovate and bring to market new chemicals and products through a flexible, targeted review process." Senate Report at 14. It also said, "S. 697 does not amend TSCA's existing policy provisions in Section 2(b), indicating the Committee's intent to leave intact existing TSCA policy relating to … the exercise of EPA's authority in a manner that does not create unnecessary economic barriers to technological innovation." *Id.* at 7. Senator Vitter explained, "Protecting innovation and not materially altering the new chemicals process was a critical part of the final compromise." 162 Cong. Rec. S3520 (daily ed. June 7, 2016).

A. SNURs Are Effective in Protecting Health and the Environment

1. SNURs Protect Against Changes Raising Health or Environmental Concerns

SNURs are effective in protecting against risks to health and the environment because they restrict the activities of both PMN submitters and of potential future manufacturers and processors. Walls Decl. ¶ 31.

SNURs are the counterpart to PMNs in almost every way. As explained above, *see* p. 18, *supra*, they bar both PMN submitters and other manufacturers and processors of a PMN substance from engaging in significant new uses (failing to protect against health and environmental concerns) unless and until EPA reviews a SNUN (the same form as a PMN); makes the same risk determination as for a PMN; and issues a section 5(e) order if it makes a "may present" determination.[21] EPA may adopt a SNUR expeditiously and on the basis of "concerns" rather than any risk determination.

Intervenor SCHF asserts that the PMN submitter may change the exposure controls in its PMN or amended PMN after EPA completes its review. Petitioner asserts that potential future manufacturers and processors may change the conditions of use from those in the PMN or amended PMN. SNURs are available

[21] *See* 55 Fed. Reg. 17377, 17378 (Apr. 24, 1990) ("Persons subject to this SNUR must comply with the same notice requirements and EPA regulatory procedures as submitters of PMNs under section 5(a)(1) of TSCA.").

to address such changes, taking into account whether such changes raise health or environmental concerns. *See* p. 43, *supra*.

2. SNURs Are Binding

Petitioner improperly asserts that section 5(e) orders are binding on the PMN submitter, but SNURs are somehow less so. Pet. Br. at 38-39. Intervenor SCHF further asserts that "[t]he activities they describe as 'significant new uses' are not prohibited." Intv. Br. at 50. This is incorrect and inconsistent with the statute. Section 5(a) provides that "no person" may engage in a significant new use as defined in a SNUR; this includes both PMN submitters and potential future manufacturers and processors. Section 15(1) makes violation of this prohibition an unlawful act, and section 16(a) establishes a potential penalty of up to $37,500 per day for any violations.

3. SNURs May Provide a Greater Level of Protection Than Section 5(e) Orders

Petitioner and Intervenor SCHF note that a section 5(e) order must restrict actions "to the extent necessary to prevent an unreasonable risk," but SNURs do not prescribe a level of protection. Pet. Br. at 39; Intv. Br. at 50. All this means is that EPA may adopt a SNUR based on concerns without having to have sufficient information to make a "may present" determination. *See* pp. 35-36, *supra*. The significant new uses identified in a SNUR are all designed to provide protection from those concerns. They may include protections that go beyond those

"necessary to prevent an unreasonable risk," whereas as section 5(e) order is limited to protections that are "necessary." Thus, they may be even more protective than a section 5(e) order.

4. SNURs May Require Testing

Petitioner and Intervenor SCHF object that although EPA may require testing in a section 5(e) order, it cannot do so in a SNUR. Pet. Br. at 36-37, 39-40; Intv. Br. at 23, 29, 34, 44, 51-52. They are wrong. Under 40 C.F.R. § 721.80(r), EPA identifies as a potential significant new use:

> Aggregate manufacture and importation volume for any use greater than that specified in subpart E of this part for the substance unless the manufacturer or importer has submitted the results of the health or environmental effects studies identified in subpart E of this part for the substance and those studies comply with the procedures and criteria for developing and evaluating data identified in subpart E of this part for the substance.

EPA has included this testing provision in multiple SNURs.[22] EPA has also stated that "SNUN notices submitted for significant new uses without any test data may increase the likelihood that EPA will take action under section 5(e) … ." 55 Fed. Reg. 17376, 17379 (Apr. 24, 1990). This action under section 5(e) could require the development of test data. *Id*.

[22] *See*, *e.g.*, 40 C.F.R. §§ 721.2122, 721.4472, 721.5780, 721.9928, 721.10199.

5. SNURs Require Notification

Petitioner asserts that "EPA can determine whether companies subject to the consent orders are abiding by the conditions incorporated by those orders," but "EPA has little means to determine whether a manufacturer has undertaken a significant new use without the manufacturer's first providing notification." Pet. Br. at 39. This is incorrect. SNURs have an automatic notification provision, as no one may engage in a significant new use for a SNUR substance without notification.

6. SNURs Do Not Present Significant Timing Concerns

Petitioner objects to the option that EPA could adopt a SNUR before or simultaneously with the issuance of a "not likely to present" determination. It asserts, without statutory support, that SNURs "are supposed to follow the issuance of consent orders." Pet. Br. at 32. Similarly, Intervenor SCHF asserts that the SNUR provisions "do not apply to 'new chemical substances' and thus come into play *after* a chemical has completed PMN review." Intv. Br. at 47. There is no statutory requirement that EPA adopt SNURs only for chemical substances already on the Inventory. EPA has issued numerous SNURs for substances for which the PMN submitter has not submitted a Notice of Commencement, which is the trigger for EPA to add the substance to the Inventory. Walls Decl. ¶ 40.

Section 5(a)(1)(i) (relating to PMNs) refers to "a new chemical substance," while section 5(a)(1)(ii) (relating to SNURs) refers to "any chemical substance." The term "chemical substance" is defined broadly in section 3(2), 15 U.S.C. § 2602(2). It does not limit "chemical substance[s]" to those on the Inventory (*i.e.*, does not require they be "new chemical substance[s]"). Thus, EPA may adopt a SNUR for a PMN substance before or at the time that it makes a "not likely to present" determination for that substance.

Petitioner and Intervenor SCHF point to section 5(f)(4), 15 U.S.C. § 2604(f)(4), as support for their argument that EPA cannot adopt a SNUR for a new chemical substance. Pet. Br. at 32; Intv. Br. at 47-48. However, section 5(f)(4) relates to the situation where EPA has already made a "may present" determination and issued a section 5(e) order. It has no relevance to EPA's ability to adopt a SNUR before or at the time it makes a "not likely to present" determination.

Intervenor SCHF also objects to EPA considering the later adoption of a SNUR when making a "not likely to present" determination, arguing that EPA "cannot condition" such a determination "on the possibility of a future SNUR." Intv. Br. at 47. As explained at p. 35, *supra*, however, when EPA considers the "reasonably foreseen" conditions of use, it is considering possible actions by the PMN submitter or potential future manufacturers and processors. If EPA were to

adopt a SNUR for the PMN substance, after its effective date those persons would be required to keep their conditions of use consistent with the SNUR, unless and until EPA gives them authorization to change. Such a SNUR would thus impact the "reasonably foreseen" conditions of use. EPA may lawfully consider a potential future SNUR when it makes its risk determination "under the conditions of use."

Petitioner and Intervenor SCHF also complain that EPA may not adopt a SNUR for a PMN substance for an extended period after it completes its review of that substance, during which interval other manufacturers and processors could begin manufacture or processing of the substance without restriction. However, for several practical reasons, persons other than the PMN submitter are very unlikely to begin to manufacture or process the PMN substances shortly after EPA completes its review. Walls Decl. ¶¶ 29-36.

Petitioner and Intervenor SCHF also object that the effective date of a SNUR might be delayed several months past the date of a direct final rule's publication, stating that if someone provides an intent to submit an adverse comment for a SNUR, EPA must withdraw that direct final SNUR and publish a proposed SNUR. *See* 40 C.F.R. § 721.170(d)(4)(B). Pet. Br. at 37; Intv. Br. at 49. However, EPA's policy is to designate a use as a significant new use "as of the date of public release" of the direct final rule, even if subsequently it must go

through full notice-and-comment rulemaking. This means that if any person were to begin engaging in a significant new use after the date of publication of the direct final SNUR, it would have to cease doing so as soon as the proposed SNUR became effective. *See, e.g.*, 83 Fed. Reg. 37702, 37717 (Aug. 1, 2018). This is a powerful incentive for persons not to begin engaging in the significant new use. In practice, manufacturers and processors do not begin engaging in a significant new use as designated in a SNUR that has not yet become effective. Walls Decl. ¶ 33.

The PMN submitter is bound to implement the controls in its PMN or amended PMN pursuant to the certification statement in its PMN. Moreover, when EPA determines that a PMN substance is a candidate for a non-order SNUR, it notifies the PMN submitter before the end of the PMN review period and describes its concerns and the activities under consideration as significant new uses. 40 C.F.R. § 721.170(d)(2). With the PMN submitter on notice of a prospective non-order SNUR for its PMN substance, it has a strong disincentive to begin engaging in the significant new use, knowing that such use will be prohibited. Walls Decl. ¶ 32.

As for a potential future manufacturer or processor, it faces many practical delays in being able to begin manufacture or processing following the end of the PMN review period. First, it cannot begin until EPA adds the new chemical

substance to the Inventory. This will not happen until the PMN submitter chooses to begin manufacture and then submits a Notice of Commencement. 40 C.F.R. § 720.102. Not infrequently, PMN submitters wait months or years before commencing manufacture. Walls Decl. ¶¶ 28, 34.

Second, the prospective manufacturer or processor will not learn of the Notice of Commencement until EPA publishes a notice of its receipt of the notice. EPA typically publishes such notices about three months after the month in which EPA received the Notice of Commencement. Walls Decl. ¶ 35.

Third, if the notice reports a generic name, which is very common, the prospective manufacturer or processor still will not know the specific chemical identity of the PMN substance. Walls Decl. ¶ 36. To find out that identity, such entities must prepare and submit a notice of bona fide intent to manufacture the chemical they believe to be covered by the Notice of Commencement. This bona fide notice requires analytical results on a sample of the material. 40 C.F.R. § 720.25. EPA must then review and respond to the bona fide notice. All of this takes months or longer to complete. Walls Decl. ¶¶ 36-37.

Accordingly, as a practical matter, it is highly likely no other manufacturer or processor will engage in a significant new use for an extensive period after EPA makes its "not likely to present" determination. Although it is possible that another manufacturer or processor might do so, EPA may reasonably conclude that

the probability that another manufacturer or processor would engage in a significant new use before it can adopt a SNUR is low, such that the PMN substance is "not likely to present an unreasonable risk."

B. EPA's Pre-TSCA Amendment Experience Shows That the Draft Framework Document Would Protect Health and the Environment

The draft Framework Document advises that EPA may resume issuing non-order SNURs and making risk determinations based in part on information in amended PMNs. EPA has done both for decades. *See* pp. 12-13, *supra*. That EPA may resume those activities indicates that EPA has repeatedly found that they protect health and the environment.

"It has been said that the life of the law is experience." *Johnson v. United States*, 135 S. Ct. 2551, 2560 (2015).[23] EPA's long experience with non-order SNURs, including those based on amended PMNs, is strong evidence that these provisions of the draft Framework Document would protect health and the environment. This experience further demonstrates the importance of reading section 5 as a whole, which Petitioner and Intervenor SCHF have failed to do.

[23] *Cf.* Oliver Wendell Holmes, Jr., *The Common Law* (1881) at 1 ("The life of the law has not been logic: it has been experience.").

VI. PETITIONER AND INTERVENOR SCHF HAVE NOT SUPPORTED THEIR FACIAL CHALLENGE TO THE DRAFT FRAMEWORK DOCUMENT

Finally, Petitioner and Intervenor SCHF have mounted a facial challenge to the draft Framework Document. This challenge fails because they have not established, or even asserted, that the draft Framework Document is inconsistent with TSCA under all the circumstances in which it might be applied.

Petitioner and Intervenor SCHF could not challenge the draft Framework Document "as applied," as the draft is not final, and EPA has not applied it. Walls Decl. ¶¶ 17-19, 39. They chose to challenge it nonetheless and therefore bear the "heavy burden" of demonstrating that the draft Framework Document is facially invalid. *United States v. Salerno*, 481 U.S. 739, 745 (1987).

A party making a facial challenge "must establish that no set of circumstances exists under which the Act would be valid." *Copeland v. Vance*, 893 F.3d 101, 113 (2d Cir. 2018), *citing United States v. Salerno*, 481 U.S. 739, 745 (1987); *see also Reno v. Flores*, 507 U.S. 292, 301 (1993) (holding that a litigant bringing a statutory challenge to a regulation "must establish that no set of circumstances exists under which the regulation would be valid"). In other words, Petitioner and Intervenor SCHF must demonstrate that the draft Framework Document violates the statute "in all of its applications." *Washington State Grange v. Washington State Republican Party*, 552 U.S. 442, 449 (2008).

Petition and Intervenor SCHF have failed to demonstrate that the draft Framework Document is contrary to law under any conceivable application or set of circumstances. *United States v. Salerno*, 481 U.S. at 745 (explaining that "[t]he fact that [a law] might operate unconstitutionally under some conceivable set of circumstances is insufficient to render it wholly invalid…."). Instead, they have identified certain provisions of the draft Framework Document to which they object, and point to hypothetical applications that might be inconsistent with the statute. The draft Framework Document, however, does not establish any binding requirements on EPA or stakeholders. It merely sets forth a flexible "working approach" that EPA "expects to evolve." Draft Framework Document at 1. Petitioner and Intervenor SCHF cannot maintain that the application of the draft Framework Document under any set of circumstances would contradict TSCA.

Petitioner and Intervenor SCHF wrongly assert that the draft Framework Document should be set aside in its entirety because certain provisions as applied might be contrary to TSCA. Even if a conceivable application of a particular provision in the draft Framework Document were found to be invalid, that would not render the entire document invalid. *United States v. Booker*, 543 U.S. 220, 275 (2005) ("[I]t is abundantly clear that the fact that a statute, or any provision of a statute, is unconstitutional in a portion of its applications does not render the statute or provision invalid."). Petitioner and Intervenor SCHF do not object to

some provisions of the draft Framework Document, such as those indicating that EPA would issue a section 5(e) order under certain circumstances. Draft Framework Document at 3. Thus, they cannot support a facial challenge to invalidate the draft Framework Document as a whole.

CONCLUSION

The Court should dismiss the petition for review because the Petitioner has not demonstrated standing. Moreover, the draft Framework Document is not final agency action nor a legislative rule subject to notice-and-comment procedures. Even if it were subject to such procedures, EPA is in the midst of a notice-and-comment process. On the merits, the draft Framework Document is consistent with TSCA and would, if implemented, protect health and the environment. Finally, this facial challenge to the draft Framework Document fails because Petitioner and Intervenor SCHF have not demonstrated, let alone tried to demonstrate, that the draft is unlawful in all its applications. For all these reasons, the petition should be denied.

Dated: August 14, 2018

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE WITH
FEDERAL RLE OF APPELLATE PROCEDURE 32(A)

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

I further certify that this brief complies with the type-volume limitation of Second Circuit Rule 32.1(a)(4)(A) because it contains 13,315 words, excluding parts of the document exempted by Fed. R. App. P. 32(f).

Dated: August 14, 2018

/s/Daniel M. Krainin
Daniel M. Krainin

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 August 14, 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.

/s/ Daniel M. Krainin
Daniel M. Krainin

18-25

IN THE

United States Court of Appeals

FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL,

Petitioner,

SAFER CHEMICALS HEALTHY FAMILIES,

Intervenor,

—v.—

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent,

AMERICAN CHEMISTRY COUNCIL,
NATIONAL ASSOCIATION OF MANUFACTURERS,

Intervenors.

ON PETITION FOR REVIEW OF AGENCY ACTION OF THE
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

ADDENDUM

UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL, *Petitioner*, SAFER CHEMICALS HEALTHY FAMILIES, *Intervenor*, v. U.S. ENVIRONMENTAL PROTECTION AGENCY, *Respondent*, AMERICAN CHEMISTRY COUNCIL, NATIONAL ASSOCIATION OF MANUFACTURERS, *Intervenors*.	Case No. 18-25

DECLARATION OF MICHAEL P. WALLS

I, Michael P. Walls, hereby state as follows:

1. I am employed by the American Chemistry Council (ACC). I make this declaration in support of the brief that ACC is filing.

2. For more than 30 years, I have had a range of legal, policy and business responsibilities for ACC. Currently, I am Vice President - Regulatory and Technical Affairs, and have primary responsibility for ACC's policy development. I have managed ACC's policy function for over a decade, with responsibility for ACC policies concerning chemical regulation and science/science policy, among other matters. Through my work at ACC, I have developed broad experience across a wide range of U.S. domestic

chemical regulatory issues, including the Toxic Substances Control Act (TSCA) and the 2016 amendments to the law made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).

3. I am a 1980 graduate of the Georgetown University School of Foreign Service and a 1984 graduate of the Syracuse University College of Law. I also received an MBA from the Georgetown University Graduate School of Business in 1999. I began work at ACC in the Office of General Counsel in 1986, where I first provided legal advice on a range of international environmental, trade and product regulation issues. Before joining ACC, I was in private law practice in Washington, D.C., and I served as a legislative assistant on the staff of U.S. Senator Jim Sasser.

4. ACC is one of America's oldest trade associations, representing a diverse group of nearly 170 companies in the $768 billion business of United States chemistry. This industry creates the building blocks for 96% of all manufactured goods. Chemistry is responsible for more than 25% of the U.S. gross domestic product, accounts for 14% of all U.S. exports, provides nearly 15% of the world's chemicals, and supports over 800,000 American jobs — while indirectly supporting millions more jobs across the county in businesses that formulate, distribute, and use or rely on chemicals.

5. ACC's members include leading companies of all sizes, engaged in every aspect of the business of chemistry, including chemical manufacturing, transportation and distribution, storage and disposal, sales and marketing, consulting, use, logistics and equipment manufacturing. Because TSCA applies to virtually all chemical substances and mixtures, each and every one of ACC's members is directly regulated by TSCA.

6. ACC's mission is to engage with and advocate on behalf of ACC's members through legislative, regulatory and legal advocacy, communications and scientific research. This includes participating in the development of policies, guidance documents, rules and other regulatory matters by the United States Environmental Protection Agency (EPA) that significantly affect ACC's member companies, as well as related litigation.

7. As part of my responsibilities for ACC, I personally developed a working knowledge and understanding of the National Association of Manufacturers (NAM) and its interest in the draft Framework Document. The NAM has interests similar to ACC because its members are involved in manufacturing of all types, and the business of chemistry creates the building blocks for 96% of all manufactured goods.

8. The NAM is the largest manufacturing association in the United States, representing small and large manufacturers in every industry sector and in

all 50 states. Manufacturing employs more than 12 million people, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for more than three-quarters of all private sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the U.S.

9. ACC and NAM have a substantial and direct interest in EPA's implementation of the New Chemicals Review Program and in the outcome of any litigation that would affect EPA's work in that Program. ACC's and NAM's interest includes EPA's description of the new chemicals review process embodied in the Framework document.

10. The Petitioner has objected to both the process EPA is following and the substance of EPA's Framework document. Based on my experience, I believe that the Court's decision in this litigation will directly impact ACC and NAM members, who manufacture, distribute, supply, formulate, use, or rely on chemicals that EPA evaluates under the Framework.

11. Further, in my experience, any impact on availability of chemicals and innovations in chemistry will be felt in turn by the many downstream users of ACC and NAM members' products and ultimately the final consumers.

12. The LCSA was signed into law on June 22, 2016, amending TSCA. ACC had long urged Congress to update the law to keep pace with scientific advancements and ensure that chemical products are safe for their intended uses while also encouraging innovation and protecting American jobs. ACC strongly supported the new amendments. Congress passed the amendments with strong bipartisan support because they delivered long-needed reforms and improvements to TSCA. I was directly and substantively involved in the negotiations that led to the amendments, on ACC's behalf.

13. A few months after enactment of the LCSA, EPA announced a public meeting and comment period to address how EPA would implement amended section 5. 81 Fed. Reg. 86713 (Dec. 1, 2016). At the ensuing December 14, 2016 public meeting, EPA staff made presentations on how EPA would interpret the amended section 5 and how EPA would implement it. ACC submitted written comments in January 2017. Among the presentations were those of Dr. Maria Doa, Director of the Chemical Control Division, Office Pollution Prevention and Toxics (OPPT), in the Office of Chemical Safety and Pollution Prevention at EPA, and Dr. Tala Henry, Director of the Risk Assessment Division of OPPT. Their presentations are available on EPA's website at

https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/public-meeting-reviewing-new-chemicals-under-toxic.

14. On November 6, 2017, EPA announced a second public meeting and comment period to address EPA's implementation of the amended section 5, to be held on December 6, 2017. The meeting announcement referred to "EPA's draft New Chemicals Decision-Making Framework." 82 Fed. Reg. 51415 (Nov. 6, 2017). I will refer to that document as the "draft Framework Document."

15. EPA posted the draft Framework Document on its website on November 7, 2017. The draft Framework Document incorporated some of the interpretations and implementation process presented at the December 2016 meeting.

16. At the December 6, 2017 public meeting, EPA discussed the draft Framework Document and received oral comments on it. Both Petitioner Natural Resources Defense Council (NRDC) and Intervenor Safer Chemicals, Healthy Families (SCHF) made oral comments. In January 2018, NRDC and SCHF followed up with joint written comments. ACC also submitted written comments. ACC representatives attended the December 6, 2017 meeting and understood the five-page draft Framework Document to be a draft, non-binding, policy statement.

17. To my knowledge EPA has not produced a final Framework Document, nor has it implemented the document. It remains a draft. EPA has issued few, if any, "not likely to present" determinations based on exposure controls in a premanufacture notice (PMN) or amended PMN. EPA posts summaries of the reasoning supporting its "not likely to present" determinations at https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/chemicals-determined-not-likely. These include determinations for Microbial Commercial Activity Notices (MCANs) (for intergeneric microorganisms, designated by "J-") and for PMNs (designated by "P-").

18. My review of EPA's explanations for these "not likely to present" determinations for PMNs shows that they overwhelmingly were issued for PMN substances for which EPA considered that the PMN substance has low human hazard and low environmental hazard. For example, EPA has stated in many cases that it "believes that [a] chemical substance would be unlikely to present an unreasonable risk even if exposures were high," where the substance poses a low hazard to human health and even high concentrations of the substance would not create a concern. In only a few instances has EPA made a statement such as that "EPA expects that workers will use adequate personal protective equipment."

19. In a recent "not likely to present" determination for PMN P-118-16-0510 (Aug. 1, 2018), https://www.epa.gov/sites/production/files/2018-08/documents/p-16-0510_determination_non-cbi_final.pdf, EPA identified low to moderate environmental hazards and some health hazards. These qualified as "potential concerns" "depending on the extent of exposure." EPA identified no "known" or "reasonably foreseen" conditions of use, and explained the multiple sources it considers in identifying "reasonably foreseen" conditions of use. EPA stated that it based its determination in this case on the "intended conditions of use," which it found were "not likely to present an unreasonable risk" for reasons explained in the determination. EPA actually went beyond the "intended" conditions of use, which were based on importation of a 50% solution of the PMN substance and use in a 2% solution. It found that a worst-case scenario of a 100% solution would still be "unlikely to present an unreasonable risk."

20. I have seen EPA routinely differentiate among concerns that it may have for PMN substances. For example, EPA issued a policy statement entitled "TSCA New Chemicals Program (NCP) Chemical Categories" (2010), https://www.epa.gov/sites/production/files/2014-10/documents/ncp_chemical_categories_august_2010_version_0.pdf. It indicates that, in the absence of additional information, EPA considers that

PMN substances that are cobalt compounds present "moderate concern for acute toxicity to fish; moderate concern for acute toxicity to daphnids; high concern for toxicity to green algae; moderate concern for chronic toxicity to fish; high concern for chronic toxicity to daphnids; high concern for toxicity to green algae …." I consider that these degrees of concern reflect EPA's judgments about the extent to which concerns that it may have about a PMN substance may impact its risk determinations under what is now section 5(a)(3).

21. A further example appears in EPA's explanation for its "not likely to present" determination for PMN P-18-014 (July 27, 2018), https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/tsca-section-5a3c-determination-91, in which EPA summarized its reasoning: "Although EPA estimated that the new chemical substance would be very persistent, this did not indicate a likelihood that the chemical substance would present an unreasonable risk, given that the chemical substance has low potential for bioaccumulation, low human health hazard, and low environmental hazard." EPA identified persistence as a concern, but determined that other factors countered that concern sufficiently that it could make a "not likely to present" determination.

22. From my experience, I understand that EPA implements the New Chemicals Review Process on the basis of the statutory provisions in section 5. The PMN regulations in 40 C.F.R. Part 720 are primarily procedural requirements addressed to PMN submitters. They do not address how EPA conducts its New Chemicals Review Process. The PMN requirements of section 5 went into effect on July 1, 1979. 44 Fed. Reg. 28564 (May 15, 1979). Except for a few stayed provisions, Part 720 took effect more than four years later, on October 26, 1983. 48 Fed. Reg. 41132 (Sept. 13, 1983). During that period EPA had no PMN regulations at all. EPA has not adopted any PMN regulations since the June 22, 2016 enactment of the LCSA. The PMN regulations do not address how EPA will evaluate PMN substances or make its risk determinations. Instead, EPA makes its risk determinations on the basis of the statutory provisions of section 5.

23. In my experience, after the end of their respective PMN review periods, PMN submitters implement the exposure controls described in their PMNs or amended PMNs. A PMN describes a variety of exposure controls, including production volumes, anticipated releases and release points, personal protective equipment, engineering controls, uses, numbers of

workers exposed, control technology and efficiency for environmental release and disposal.

24. An Authorized Official of every PMN submitter must certify on page 2 of the PMN form that "to the best of my knowledge and belief" "all information provided in this notice is complete and truthful as of the date of submission." The PMN form accompanies that statement with the following admonition: "The accuracy of the statements you make in this notice should reflect your best prediction of the anticipated facts regarding the chemical substance described herein. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 USC 1001." Based on my discussions with ACC members, ACC members take the certification requirement and that admonition seriously. They regard both as applicable to an amended PMN, not just to the original submission, and applicable at the end of the review period as well as at the beginning of it. They understand that they may be at risk of civil enforcement or criminal prosecution if they were to fail to implement and follow the exposure controls in their PMNs or amended PMNs after the end of the PMN review period until circumstances justifying a change occur (e.g., a surge in demand leading to production in amounts greater than predicted in the PMN).

25. Based on my discussions with ACC members, PMN submitters regard exposure controls in their PMNs as effectively binding once they begin non-exempt commercial manufacture, unless and until circumstances change significantly from those anticipated during the review period. This typically occurs, if at all, months or years after the end of the review period. An example of a change that could occur is unexpectedly high market demand for the substance, such that the anticipated production volumes stated in the PMN are exceeded.

26. When EPA indicates that it plans to issue a section 5(e) order to a PMN submitter, EPA and the PMN submitter negotiate the terms of that order. I have been informed by ACC members that this process typically takes months, and that in some cases it takes several months or quite a bit longer (well over a year). During this period the PMN submitter agrees to suspend the running of the statutory 90-day PMN review period. In terms of calendar days, however, the days needed for EPA to prepare a draft order and submit it to the PMN submitter, for the PMN submitter to review it and submit comments to EPA, for EPA to review the comments and prepare a revised order, then for EPA to issue an order often results in PMN review periods extending for hundreds of calendar days.

27. Following the end of the review period for its PMN, a PMN submitter may begin manufacture of the PMN substance for non-exempt commercial purposes, subject to any section 5(e) order. Once it begins non-exempt manufacture, it must submit a notice of commencement of manufacture (Notice of Commencement or NOC) to EPA within 30 days of commencing manufacture. 40 C.F.R. § 720.102.

28. Based on my experience, however, the PMN submitter does not always commence non-exempt manufacture immediately after the end of the PMN review period, for commercial or other reasons. Instead, sometimes months or years may pass before the PMN submitter commences non-exempt manufacture. Only after it begins non-exempt manufacture will the PMN submitter submit a Notice of Commencement to EPA.

29. Based on my knowledge of the industry, and for practical reasons described in detail later in my declaration, persons other than the PMN submitter are unlikely to manufacture or process a PMN substance for months or years after the end of the PMN review period, thus generally allowing time for EPA to adopt a SNUR for the substance before they place it on the market.

30. EPA regulations call for promulgation of a SNUR within a few months of deciding that one is needed. Where EPA has issued a section 5(e) order,

the regulations call for publication of a SNUR for the substance within 180 days of EPA's receipt of the PMN submitter's Notice of Commencement for the substance. 40 C.F.R. § 721.160(d)(1). Where EPA has not issued a section 5(e) order, the regulations call for publication of a SNUR for the substance within 270 days of EPA's receipt of the PMN submitter's Notice of Commencement for the substance. 40 C.F.R. § 721.170(e)(1). In my experience, EPA usually adopts a SNUR for a PMN substance after the end of the PMN review period.

31. Based on my knowledge of the industry, SNURs are effective in regulating the activities of prospective and actual manufacturers and processors of SNUR substances. A SNUR identifies one or more significant new uses of a chemical substance, typically a substance that has completed PMN review. No manufacturer or processor of a SNUR substance (other than a PMN submitter who is subject to a section 5(e) order for the SNUR substance) may engage in any significant new use identified in the SNUR without first submitting a significant new use notice (SNUN) to EPA and waiting until the end of the applicable review period. The SNUN review process is virtually identical to the PMN review process. Thus, both the PMN submitter (in cases where no section 5(e) order is issued) and other manufacturers and processors of the SNUR substance are barred from

engaging in the significant new uses for the substance unless and until they submit a SNUN and EPA completes its review.

32. EPA regulations call for EPA to notify a PMN submitter prior to the end of the review period if the PMN substance is a candidate for a SNUR but not a section 5(e) order, and to inform the PMN submitter of the activities under consideration as significant new uses. 40 C.F.R. § 721.170(d)(2). I have been informed by ACC members as part of my work responsibilities that where EPA so informs a PMN submitter, after the end of the PMN review period and before EPA's adoption of a SNUR, the PMN submitter will likely refrain from engaging in the activities identified as potential significant new uses. I further understand from ACC's members that where EPA so informs a PMN submitter, the agency does later adopt a SNUR for the PMN substance.

33. From my experience at ACC and in discussions with companies in the industry, when EPA publishes a direct final SNUR for a PMN substance that identifies significant new uses, persons other than the PMN submitter will not begin to engage in those uses for that substance notwithstanding the fact that the SNUR is not yet effective. Instead, they will anticipate that the SNUR will become effective and conclude that they have no

incentive to begin engaging in such uses, knowing that they would have to cease doing so once the SNUR does become effective.

34. Once the PMN review period ends, it will take months or years for other potential manufacturers or processors to learn that the PMN substance is on the TSCA Inventory. First, the PMN submitter must commence manufacturer of the PMN substance and submit a Notice of Commencement to EPA.

35. Second, EPA must publish a notice announcing that a Notice of Commencement has been received for the PMN substance. EPA typically publishes these notices about three months after receiving the Notice of Commencement. For example, EPA published a notice identifying the PMNs for which it received Notices of Commencement in April 2018 at 83 Fed. Reg. 34843 (July 23, 2018), three months after its receipt of those Notices of Commencement. As noted above, in my experience PMN submitters sometimes may not submit Notices of Commencement for months or years after the close of their PMN review periods.

36. Third, the chemical identity provided in the notice is often a generic name rather than a specific chemical identity. This is illustrated in the July 23, 2018 notice mentioned above. Of the 16 Notices of Commencement mentioned, 11 had generic chemical identities and 5 had specific chemical

identities. EPA posts the TSCA Inventory of Existing Chemical Substances (Inventory) on its website in two parts. (The Inventory is available at https://www.epa.gov/tsca-inventory/how-access-tsca-inventory.) The public part contains specific chemical identities where those identities have not been claimed to be confidential. The confidential part contains the chemical identities that have been claimed to be confidential. The public does not have direct access to the confidential Inventory. EPA does post a public version of the confidential Inventory; it provides generic names rather than specific chemical identities. Members of the public may learn whether or not a particular chemical substance is on the confidential Inventory by submitting to EPA a bona fide notice of intent to manufacture the substance (BFIM). Where EPA provides only a generic name for a PMN substance in a public notice, a potential manufacturer or processor has no way of confirming the identity of the PMN substance other than by submitting a BFIM for what it believes is the PMN substance to EPA.

37. Preparation of a BFIM requires detailed information on the chemical substance to be manufactured, including analytical chemistry data on the substance. I understand from ACC members that it can take a month or longer to prepare the BFIM. Once a BIFM has been submitted, EPA can

take a month or longer to respond. EPA's response will be whether or not the chemical substance is on the TSCA Inventory, but it will not connect it to a specific PMN number.

38. Statistics on EPA's website indicate that before enactment of the LCSA, in the period from 1979 through June 21, 2016, EPA received 40,151 PMNs, of which 14,206 (35%) were added to the TSCA Inventory through submission of an NOC. During this time, EPA issued 1,729 section 5(e) orders. Of these, 739 were later associated with a SNUR. In addition to these 739 SNURs, an additional 1,457 new chemical substances were regulated by EPA with SNURs. EPA posted these statistics at the following website: https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review#tab-2.

39. Since enactment of the LCSA, EPA has published direct final rules adopting SNURs for 268 chemical substances. SNURs for 57 chemical substances appeared at 81 Fed. Reg. 81250 (Nov. 17, 2016). SNURs for 37 chemical substances appeared at 82 Fed. Reg. 44079 (Sept. 21, 2017). SNURs for 29 chemical substances appeared at 82 Fed. Reg. 48637 (Oct. 19, 2017). SNURs for 145 chemical substances appeared at 83 Fed. Reg. 37702 (Aug. 1, 2018). The Federal Register notices for these SNURs identify whether the SNUR substances were the subject of a section 5(e)

order. For those SNUR substances that were not the subject of a section 5(e) order, EPA had not previously made a "not likely to present" determination. Instead, EPA had completed its review of the PMN substances in the New Chemicals Review Process prior to enactment of the LCSA, which introduced the "not likely to present" determination. The preambles to these non-order SNURs include the statement "Therefore, EPA has not determined that the proposed manufacturing, processing, or use of the substance may present an unreasonable risk." That statement also appeared in preambles to numerous direct final SNURs prior to enactment.

40. EPA has adopted SNURs for chemical substances that are not on the Inventory. For example, its first direct final rule adopting SNURs indicated that for none of the SNURs in that rulemaking had the PMN submitters submitted NOCs for their PMN substances, and thus none of those substances was on the Inventory. 55 Fed. Reg. 17376, 17380 (Apr. 24, 1990).

In accordance with 28 U.S.C. § 1746, I declare under penalty of perjury that, to the best of my knowledge, the foregoing is true and correct.

Executed this 9th day of August 2018.

Michael P. Walls