IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

No. 18-25

NATURAL RESOURCES DEFENSE COUNCIL,

Petitioner,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

On Petition For Review Of Agency Action
Of The United States Environmental Protection Agency

PAGE PROOF BRIEF OF U.S. ENVIRONMENTAL PROTECTION AGENCY

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TABLE OF CONTENTS

TABLE OF AUTHORITIES

Cases

Statutes

Code of Federal Regulations

Federal Register

STATEMENT OF JURISDICTION

This Court has subject-matter jurisdiction to review a claim under the Toxic Substances Control Act, if the petitioner has standing, *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 408-09 (2013), and the challenged conduct constitutes a final "rule" of the U.S. Environmental Protection Agency, 15 U.S.C. § 2618(a)(1)(A). Both requirements are essential to this Court's jurisdiction, and neither is met here.

The petitioner lacks standing because it has not alleged an injury in fact caused by the challenged guidance document. *See infra* at I.

Jurisdiction is also absent because the guidance document at issue is not a legislative rule, but is instead an unreviewable policy statement. *See infra* at II.

STATEMENT OF THE ISSUES

Before a new chemical substance may be manufactured, the Toxic Substances Control Act (TSCA) requires the manufacturer to submit to EPA a pre-manufacture notice describing, for example, the intended use of the chemical substance and its characteristics. The Act then requires EPA to assess and determine the risks of that chemical substance. Among other things, the determination may allow for manufacture

without limitations, or may prohibit or limit manufacture, or require testing. In November of 2017, EPA posted and sought comment on a draft framework document (Framework), describing its working approach to making these determinations. The Framework made clear that it was not intended as a definitive interpretation of the Act's requirements, and that the Agency retained discretion to evaluate notices on a case-by-case basis.

This case presents three issues:

I. Whether the petitioner has Article III standing to bring this challenge where it has not alleged a certainly impending injury that is caused by the Framework.

II. Whether the Framework constitutes a final, legislative rule reviewable under TSCA where it is not binding on EPA or anyone else, and merely provides information about one approach the Agency may follow in appropriate circumstances.

III. Whether the Framework is consistent with the requirements of TSCA where the Act confers on EPA discretion to determine whether a new chemical substance is likely to present unreasonable risk under its conditions of use.

PERTINENT STATUTES AND REGULATIONS

The relevant statutes and regulations that are not included in the petitioner's addendum are included in an addendum to this brief.

STATEMENT OF THE CASE

A. Statutory and Regulatory Background.

1. Judicial review under the Toxic Substances Control Act.

As relevant here, Toxic Substances Control Act (TSCA) provides for judicial review in the "United States Court of Appeals for the District of Columbia Circuit or for the circuit in which [the petitioner] resides" of rules promulgated under §§ 2601-29, or orders "issued under section 2603, 2604(e), 2604(f)." 15 U.S.C. § 2618(a)(1)(A). A petition must be brought "not later than 60 days after the date on which the rule is promulgated," or from which the order was issued. *Id.*

2. TSCA section 5.

"Congress enacted TSCA in 1976 with the express purpose of limiting the public health and environmental risks associated with exposure to and release of toxic chemical substances and mixtures." *Physicians Comm. For Responsible Med. v. Johnson*, 436 F.3d 326, 327 (2d Cir. 2006) (citing 15 U.S.C. § 2601). The Act instructs EPA to work

toward this purpose "in such a manner as not to impede unduly or create unnecessary economic barriers to technological innovation." § 2601(b)(3).

Section 5 of the Act, 15 U.S.C. § 2604, provides that "no person" may "manufacture a new chemical substance" unless EPA first "makes a determination" regarding that substance, and then takes "the actions required in association with that determination." To obtain a determination, a person must first submit to EPA a "pre-manufacture notice" (PMN) which sets forth, among other things, the hazards, fate, and exposure information concerning the chemical substance, as well as its intended categories of use and available data. § 2604(a)(1); 40 C.F.R. pt. 720. The pre-manufacture notice must include information "known to or reasonably ascertainable by the submitter," including, for example, the "specific chemical identity of the substance," as well as the submitter's intended categories of use. 40 C.F.R. § 720.45(f).

EPA then has ninety days (with allowable extensions), to review the pre-manufacture notice and make a risk-based determination consistent with the substantive criteria described below. 15 U.S.C. §§ 2604(a)(3), 2604(c). This requirement—that EPA must make a

determination regarding each pre-manufacture notice submitted—is new, and was imposed by the 2016 amendments to TSCA. *See* Frank R. Lautenberg Chemical Safety for the 21st Century Act, Pub. L. No. 114-182, 130 Stat. 448 (2016). Prior to the enactment of the 2016 Amendments, EPA was not required to make a determination on every pre-manufacture notice. *See* Pub. L. No. 94-469, 90 Stat. 2003, 2012 (1976). Rather, the Agency had discretion to take no action, or to make one of several specified determinations, and then initiate action if certain criteria were met. *Id*.

The Act, as amended, provides that EPA must make one of the determinations provided by the statute, including:

- The chemical substance presents an "unreasonable risk of injury to health or the environment" under its "conditions of use." 15 U.S.C. § 2604(a)(3)(A).
- The "information available" is insufficient "to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance." § 2604(a)(3)(B)(i).

- "In the absence of sufficient information" to make a reasoned evaluation, the chemical substance "may present an unreasonable risk." § 2604(a)(3)(B)(ii)(I).
- The chemical "will be produced in substantial quantities," and either "enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be substantial human exposure to the substance." § 2604(a)(3)(B)(ii)(II).
- The chemical substance is "not likely to present an unreasonable risk of injury to health or the environment" under its "conditions of use." § 2604(a)(3)(C).

The phrase "conditions of use" is a defined term. TSCA provides that a chemical substance's "conditions of use" include "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." § 2602(4).

If EPA determines that the chemical substance "is not likely to present unreasonable risk of injury to health or environment" under its

"conditions of use," then the submitter may "commence manufacture of the chemical substance." 15 U.S.C. § 2604(a)(3)(C). If EPA makes any other determination, however, the Agency must take additional steps.

Specifically, if EPA determines that the chemical substance presents an "unreasonable risk of injury to health or environment" under its conditions of use, then EPA has two options "to protect against such risk." § 2604(f). It may "issue a proposed rule . . . prohibiting or restricting the manufacture, processing, distribution in commerce," use or disposal of that chemical substance. §§ 2604(f); 2605(a). Or, the agency may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of that chemical substance. § 2604(f).

Similarly, if EPA determines that the available information is insufficient to permit a reasoned evaluation of the chemical substance, § 2604(a)(3)(B)(i) or (ii)(I), or that the chemical will be produced in substantial quantities as described in section 2604(a)(3)(b)(ii)(II), then EPA shall issue an order under section 5(e), § 2604(e), of the Act. The purpose of an order under section 2604(e) is to "prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of

such substance . . . to the extent necessary to protect against an unreasonable risk of injury to health or the environment." A section 5(e) order, § 2604(e), may further require the pre-manufacture notice submitter to perform testing regarding the chemical substance, and give this information to EPA. § 2604(e).

Once the submitter has begun to manufacture a chemical substance, that chemical substance is listed on the TSCA Chemical Substance Inventory. § 2607(b)(1). Other companies may then begin to manufacture the substance, §§ 2602(11), 2604(a), subject to any limitations imposed by EPA after a chemical substance is listed, such as restrictions imposed by rule under section 2604(a)(2), or section 2605.

One restriction on other companies is the issuance of significant new use rule (SNUR). 15 U.S.C. § 2604(a)(2). TSCA provides that EPA may promulgate a significant new use rule if a use of a chemical substance is a "significant new use" based on a "consideration of all relevant factors." *Id*. These factors include the "projected volume of manufacturing and processing," "the extent to which a use changes the type or form" or "magnitude and duration" of exposure," and the "reasonably anticipated manner and methods of manufacturing,

processing, distribution in commerce, and disposal" of the chemical substance. *Id*. Once EPA promulgates a significant new use rule, a person must seek permission from EPA to manufacture or process the chemical for the significant new use by submitting a significant new use notice to EPA. § 2604(a)(1); 40 C.F.R. pt. 721. The same agency review process that applies to pre-manufacture notices applies to significant new use notices. *See, e.g.*, 15 U.S.C. § 2604(a)(3).

B. Procedural History Relevant to This Case.

1. Issuance of Framework document for comment.

Over a year after the enactment of the TSCA Amendments, EPA announced a series of public meetings to discuss, among other things, the TSCA section 5, § 2604, review process. 82 Fed. Reg. 51,415 (Nov. 6, 2017). In conjunction with that notice, EPA issued several documents for public consideration. These documents included the guidance document at issue in this case, a five-page document entitled, "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" (Framework). *Id*., JA__. The announcement published in the Federal Register characterized the Framework as a "draft," and sought "input" from all "interested

parties." 82 Fed. Reg. 51,415. It continued that "[t]he Agency 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." *Id.*

EPA described the purpose of the Framework as "outlin[ing] EPA's approach to making decisions, on new chemical notices submitted to EPA under TSCA section 5." Framework at 1, JA__. The Agency provided that as it "continues to gain experience with new chemicals decision making under amended TSCA, it expects to evolve this working approach." *Id.*

EPA stated that the Framework laid out "general principles for making section 5 determinations and some of the factors considered." *Id.* at 3, JA__. Specifically, "[t]hese discussions are not intended to be interpretations of what is required by TSCA or the range of discretion afforded by TSCA; nor are they a recitation of the elements of a specific determination." *Id.* The document provided that "specific cases may present circumstances that are not addressed in these discussions or that warrant different approaches from those set out here." *Id.*

The Framework then explained an approach "[w]here the conditions of use identified in submissions raise risk concerns, if the submitters provide timely written amendments . . . addressing those concerns." *Id*. at 2, JA__. In those circumstances, "in general EPA will consider the conditions of use in those amended submissions to be the intended conditions of use." *Id*.

The Framework also set forth some of the considerations the Agency may take into account in making determinations that a chemical "presents unreasonable risk," and conversely, that a chemical is "not likely to present unreasonable risk." *Id*. at 1, JA__. For a "presents unreasonable risk" determination, the Agency may consider, among other things, whether the "risks under the conditions of use are above risk benchmarks," whether "[r]isk-related factors" show that "the risks are unreasonable under the conditions of use," and also, whether EPA's concerns were addressed "through amendment of the pre-manufacture notice (PMN) . . . in conjunction with the issuance of a SNUR, or issuance of a SNUR" alone. *Id*. at 4, JA__.

For a "not likely to present unreasonable risk" determination, the Framework indicated the Agency may consider, among other things,

whether the "[h]ealth and environmental risks for the conditions of use are below [the Agency's] benchmarks" or, if so, whether "other risk-related factors" like "exposure-related considerations" show that "the risks are not likely to be unreasonable." *Id.* EPA may also take into account whether "concerns regarding the conditions of use" had been "adequately addressed through amendment of the pre-manufacture notice made during the review period in conjunction with the issuance of a SNUR." Or, alternatively, whether such concerns had been adequately addressed through "issuance of a SNUR without amendment of the PMN." *Id.*

In circumstances "[w]here EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use described in a submission," the Framework stated the Agency "will assess whether those concerns can be addressed through significant new use rules." *Id.* at 2. EPA continued that the "expectation is that SNURs will generally be effective vehicles to address such concerns and that, as a general matter, EPA will address such concerns through SNURs." *Id.*

A number of parties submitted comments in response to the Framework document. *See* EPA-HQ-OPPT-2017-0585, JA__. The Agency is presently considering the comments it has received. (Decl. of J. Morris at ¶ 7, Exh. A.) EPA has not yet issued a revised version of the Framework.

2. Public meeting with stakeholders to discuss Framework.

On December 6, 2017, EPA held a public meeting to discuss the draft Framework document with stakeholders. Dr. Jeff Morris, director of EPA's Office of Pollution Prevention and Toxics, led the discussion. This included a slide presentation and a question and answer session. *See* Dec. 6, 2017 Transcript (Tr.), JA__. Dr. Morris addressed a variety of topics, including the Agency's approach to pre-manufacture notice determinations as described in the Framework. *Id.*

Dr. Morris explained the Agency's view at that time that "reasonably foreseen uses" could be addressed by issuing a significant new use rule. Tr. at 4, JA__. Then, "if anyone wants to deviate from the conditions described in the pre-manufacture notice, for which we don't have concerns," they would have to file a significant new use notice "so we can evaluate . . . whether or not [that new use] present[s] an issue."

Id. Dr. Morris stated that "we are acting on the [Framework] and governing ourselves by the framework"; while elsewhere he said that "this is an area of active discussion." *Id*. at 7, 10 JA__. He continued that "I appreciate the input we have gotten so far and I welcome more." *Id*. at 7, JA__. He also explained that he "fully expect[s] that as we take comments . . . how we describe things will change a bit." *Id*. at 10, JA__. Later, Dr. Morris also explained that using a significant new use rule to address reasonably foreseen uses was not automatic: "*should* we go the SNUR route in a particular case," then the Agency will "want to make sure [it is] very clear on how it links to what is outlined in the PMN." *Id*. at 11, JA__ (emphasis added).

3. Agency practice since issuance of Framework document.

Since the Framework was issued for comment, EPA has made 150 determinations on pre-manufacture notices under section 5(a)(3), § 2604(a)(3). (Decl. at ¶ 9.) The Agency has not yet followed the SNUR approach described in the Framework. For 19 pre-manufacture notices, the agency determined that the new chemical substance was not likely to present an unreasonable risk, § 2604(a)(3)(C). (Decl. at ¶ 10.) For none of these determinations did EPA consider whether a significant

new use rule had been issued in concluding that unreasonable risk was unlikely. (*Id.*) Additionally, for 131 determinations, EPA made a determinations under section 5(a)(3)(B), § 2604(a)(3)(B), related to the sufficiency of information regarding the substance, and then issued orders under section 5(e), § 2604(e). (Decl. ¶ 11.) The basis for a significant number of these determinations was related to the reasonably foreseen conditions of use of the new chemical substance at issue. (*Id.*) Notwithstanding the Agency's pronouncement in the Framework that it anticipated using significant new use rules in similar cases, none of these determinations followed that approach. (*Id.*)

4. The petition for review.

Natural Resources Defense Council filed a petition for review of the Framework document on January 5, 2018. Doc. Id. 2207660. Safer Chemicals Healthy Families intervened in the case in support of petitioner. Doc. Id. 2243975. The American Chemistry Council and the National Association of Manufacturers intervened in support of EPA. *Id.*

SUMMARY OF ARGUMENT

Section 5 of the Toxic Substances Control Act, 15 U.S.C. § 2604, requires EPA to assess the risks to human health and the environment of new chemical substances, and then make a determination on each substance before it may be manufactured. Petitioner challenges a five-page document entitled "New Chemicals Decision-Making Framework: Working Approach to Making Determinations under Section 5 of TSCA" (Framework), which EPA issued for public comment in November of 2017. The Framework described one approach that EPA may take in assessing the risk of a new chemical substance in appropriate cases. Petitioner asserts that this draft document constitutes a final rule that should have been promulgated through notice and comment rulemaking. Petitioner's arguments are all unavailing.

I. Petitioner lacks Article III standing to challenge the Framework. It has not established injury in fact because the Framework does not impose a certainly impending injury on its members. Rather, Petitioner's members face no injury at all, unless and until EPA applies the approach described in the Framework to an individual determination, and then the determination allows

Petitioner's members to be exposed to the chemical substance under circumstances that pose an unreasonable risk to human health. Nor has Petitioner established the element of causation. The Framework is a nonbinding policy statement that has no legal consequence and so cannot be the cause of any injury.

II. Subject-matter jurisdiction is also absent because the Framework does not constitute a final rule under TSCA, section 2618(a)(1)(A). The Framework is a non-final statement of policy that explains one possible approach that EPA may apply in an appropriate case to make a determination on a new chemical substance under TSCA section 5, 15 U.S.C. § 2604. It does not alter the legal regime established by TSCA in any respect, and leaves EPA free to exercise discretion and not follow the Framework's approach in making individual determinations. Indeed, EPA has not yet applied the approach described in the Framework to any determinations under section 5, § 2604, and has instead followed other approaches to determine whether new chemical substances present unreasonable risk, and to address concerns regarding any potential risk. Because the Framework does not create binding legal obligations for EPA or anyone

else, it is not a legislative rule and can be issued without notice and comment rulemaking.

III. The Framework is consistent with the requirements of TSCA. Section 5, § 2604, affords the EPA Administrator discretion to evaluate whether a new chemical substance poses unreasonable risk under its conditions of use. EPA may rationally take into account as part of this assessment whether a significant new use rule has been issued addressing concerns with a new chemical substance. Once a significant new use rule is issued, the rule prohibits use of a chemical substance for the identified "significant new use" until EPA makes a further determination on the chemical substance's risk. Thus, it is reasonable for EPA to consider whether a chemical substance is subject to a significant new use rule when evaluating the risk that the substance poses to human health and the environment under its conditions of use.

STANDARD OF REVIEW

Petitioner bears the burden of establishing that jurisdiction exists. *See Lunney v. United States*, 319 F.3d 550, 554 (2d Cir. 2003). The Court has "an independent obligation" to be sure of its subject-matter jurisdiction. *Dean v. Blumenthal*, 577 F.3d 60, 64 (2d Cir. 2009).

On the merits, the Court reviews whether the agency's decision is arbitrary or capricious, or otherwise not in accordance with the law. *See* 15 U.S.C. § 2618(c)(1)(A), (B); *Nat'l Ass'n of Home Builders v. EPA*, 682 F.3d 1032, 1036 (D.C. Cir. 2012) (TSCA authorizes judicial review under the standards prescribed by the APA). "Although the scope of judicial review under this standard is narrow and deferential," the agency must have "articulated a 'satisfactory explanation for its action,' including 'a rational connection between the facts found and the choice made.'" *Henley v. FDA*, 77 F.3d 616, 620 (2d Cir. 1996) (quoting *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 41 (1983)). But, a reviewing court cannot "substitute its judgment for that of the agency," "particularly when that determination is propelled by the agency's scientific expertise." *Henley*, 77 F.3d at 620, 340 F.3d at 53 (quoting *Citizens To Preserve Overton Park, Inc. v. Volpe*, 401 U.S. 402, 416 (1971)).

I. PETITIONER LACKS STANDING TO CHALLENGE THE FRAMEWORK.

To show associational standing, Petitioner must demonstrate, along with other elements, that at least one of its members "would otherwise have standing to sue in their own right." *N.Y. Pub. Interest*

Research Grp. v. Whitman, 321 F.3d 316, 325 (2d Cir. 2003). Article III standing exists where an identified member has (1) suffered an "injury-in-fact" that is "concrete and particularized," and "actual or imminent, not conjectural or hypothetical," (2) "the injury is 'fairly traceable to the challenged action,'" and that (3) "'it is likely, as opposed to merely speculative, that the injury will be redressed by a favorable judicial decision.'" *Green Island Power Auth. v. FERC*, 577 F.3d 148, 159 (2d Cir. 2009) (citing *Friends of the Earth v. Laidlaw Envtl. Servs. (TOC) Inc.*, 528 U.S. 167, 180–81 (2000)). "Significantly, when a plaintiff is not himself the object of the government action or inaction he challenges, standing is not precluded, but it is ordinarily 'substantially more difficult' to establish.'" *Martin v. SEC*, 734 F.3d 169, 173 (2d Cir. 2013) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 562 (1992)).

In this case, Petitioner is an environmental organization that alleges injuries to its members based on increased risk from exposure to harmful chemical substances. Specifically, Petitioner asserts that its members are "concerned about their risk of exposure to new chemicals" that may be approved "under" the Framework. (Pet. Br. at 55.) Petitioner further contends that this injury is caused by the Framework

because if EPA were to issue "enforceable orders to address the Agency's concerns with the environmental and health risks presented by new chemical substances, then NRDC's members would not face the same health and environmental risks." (*Id.* at 56.)[1]

Petitioner has failed to meet its burden and has not shown that the Framework has caused its members an imminent injury in fact. Where a petitioner alleges an injury that has not yet occurred, it confronts a more rigorous burden to establish standing: the "threatened injury must be *certainly impending* to constitute injury in fact." *Clapper v. Amnesty Int'l, USA*, 568 U.S. 398, 409 (2013) (citation omitted). "[A]llegations of *possible* future injury are not sufficient." *Id.*

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[1] NRDC is wrong that the approach described in the Framework is less protective than issuing an order as petitioner seeks. *See infra* at III. Nevertheless, for purposes of determining standing, the analysis "assume[s] that on the merits the [petitioner] would be successful in [its] claims." *City of Waukesha v. EPA*, 320 F.3d 228, 235 (D.C. Cir. 2003) (citing *Warth v. Seldin*, 422 U.S. 490, 502 (1975)); *Jackson-Bey v. Hanslmaier*, 115 F.3d 1091, 1096 (2d Cir. 1997).

In addition, Intervenor did not separately establish its standing. It made no argument that its members suffered an injury in fact that was caused by the Framework, or would be redressed by its vacatur. (*See* Intv. Br. at 3-4 (discussing jurisdiction).)

In *Clapper*, for example, the plaintiffs challenged a provision of the Foreign Intelligence Surveillance Act that authorized surveillance of certain communications of foreigners abroad. *Id*. at 404. The plaintiffs alleged that it was likely that their communications with their foreign contacts abroad would be intercepted by the government pursuant to authority granted by the Act, and that this interception was unconstitutional. *Id*. The Supreme Court held that the plaintiffs lacked standing, reasoning that the fact that the law "*authorizes*—but does not *mandate* or *direct*" the conduct at issue made the plaintiffs' claimed injury based on the law "necessarily conjectural." *Id*. at 412. Thus, it was speculative whether the government would intercept plaintiffs' communications in the future and, if it did, that it would rely on the law—as opposed to "some other authority"—to do so. *Id*. at 411-12.

Likewise, in *Deutsche Bank National Trust Co. v. FDIC*, 717 F.3d 189 (D.C. Cir. 2013), the D.C. Circuit held that the intervenors there lacked standing where their claimed injury of economic harm was contingent on a future event that might not occur: an adverse decision in a pending case against the FDIC, *id*. at 193. The court reasoned that

"[u]nder such circumstances, where a threshold legal interpretation must come out a specific way before a party's interests are even at risk, it seems unlikely that the prospect of harm is actual or imminent." *Id.* *See Sierra Club v. EPA*, 873 F.3d 946, 950 (D.C. Cir. 2017) (concluding petitioners lacked standing to challenge guidance document where they "failed to adduce evidence that [the guidance] will have any effect on any" individual action impacting them); *Nat. Res. Def. Council v. FDA*, 710 F.3d 71, 85-86 (2d Cir. 2013) (holding that claimed injury was too remote to confer standing where alleged harm would not take place unless "intermediate step" occurred, which was bacteria becoming resistant to antibiotics).

Here, Petitioner alleges an injury that is contingent on a series of future events—that is, at some point, EPA may apply the approach described in the Framework to an individual pre-manufacture notice determination. (Pet. Br. at 55-57.) If that happens, EPA could conclude that a chemical substance does not present an unreasonable risk based in part on the Agency's promulgation of a significant new use rule. (*Id.*) This determination, in Petitioner's view, could increase risk for its members. (*Id.*)

Petitioner's threatened injury is not "*certainly impending*," as it must be "to constitute an injury in fact." *Amnesty*, 568 U.S. at 408-09. At most, the alleged injury is merely "*possible*," which is not sufficient. *Id*. As discussed *infra* at 33-39, the Framework does not "mandate or direct" EPA to take a specific action for any pre-manufacture notice. Accordingly, the purported injury is "necessarily conjectural." *Id*. at 412.

The Framework merely provides that, if the Agency has concerns with a chemical substance's reasonably foreseen uses, EPA "will assess whether those concerns can be addressed through significant new use rules," and that the Agency's "expectation" is that the Framework's approach will be applied where appropriate. Framework at 2, JA__. The Framework does not dictate the result EPA will reach from this analysis. Nor does the Framework require that any possible concerns be addressed through a significant new use rule, rather than an order, in any particular case. *See id*. Indeed, the Framework makes clear that it does not authorize any action that would otherwise be impermissible: it is "not intended to be interpretations of what is required by TSCA or the range of discretion afforded by TSCA," and the circumstances of a

particular case may "warrant different approaches from those set out here." *Id.* at 3, JA__.

Just like in *Deutsche Bank*, Petitioner's feared injury is contingent on a "threshold legal interpretation . . . com[ing] out a specific way before a party's interests are even at risk." 717 F.3d at 193. For Petitioner to face any injury at all, EPA would first have to make a legal determination on an individual pre-manufacture notice that a new chemical substance is not likely to present unreasonable risk following the approach in the Framework. Further, that legal determination must be one that, in the absence of a significant new use rule, EPA would have made a different determination. Then, it must be likely, as opposed to speculative, that Petitioner's members will be exposed to the new chemical substance under circumstances that pose an unreasonable risk to human health.[2] And, this exposure must result

[2] Petitioner's standing allegations focus on the alleged harm to human health that may be posed by new chemical substances. (Pet. Br. at 50-55 (discussing alleged "health concerns arising from exposure" as well as "concern[ ] about the chemicals to which [the member] is exposed.") While Petitioner mentions alleged harm to the environment in passing, it does not establish that any environmental harm would affect it or its members. *See Lujan*, 504 U.S. at 564 (holding unspecified allegations of injury caused by harm to the environment "is simply not enough" to establish standing).

from the difference between the protection offered by a significant new use rule, and an order. Petitioner has not established that each of these events is likely, and so the "prospect of harm" is not "actual or imminent." *Deutsche Bank*, 717 F.3d at 193.

Indeed, Petitioner does not describe in any detail how its members would be harmed if EPA followed the Framework's approach in a particular case. This is consistent with Intervenor's concession that it would face standing hurdles if it were to challenge a determination if the Framework is applied. (Intv. Br. at 34.) Petitioner instead rests on generalities regarding the number of determinations EPA makes annually, and the importance of the section 5, § 2604, process generally. (Pets. Br. at 51.) These sweeping assertions are not grounded, as they must be, in "specifically identifiable Government violations of the law" that are certainly impending. *Lujan*, 504 U.S. at 568. Rather, they reflect a generalized concern about the TSCA section 5 program as a whole, which is not cognizable. *Id*. Accordingly, these allegations do not show that Petitioner's claimed injury from the Framework is likely.

Moreover, Petitioner ignores that EPA has made more than one hundred determinations on pre-manufacture notices since issuance of

the Framework for comment. (Decl. ¶¶ 9-11.) Notably, none of these determinations applied the approach that EPA described in the Framework. (*Id*.) That EPA has consistently applied approaches different from the approach described in the Framework makes Petitioner's alleged injury even more speculative. Thus, Petitioner has not met its burden and established an injury in fact that is caused by the Framework.[3]

[3] For similar reasons, the Petitioner has not established redressability. Because the Framework is a policy statement that does not change the requirements of TSCA, Petitioner cannot show that its alleged injury would be redressed by vacatur of the Framework. *Nat'l Wrestling Coaches Ass'n v. Dep't of Educ.*, 366 F.3d 930, 933(D.C. Cir. 2004) (holding no redressability where controlling "legal regime" would "remain in place even if the disputed [policy interpretations] were revoked").

In addition, as discussed below at __, Petitioner may challenge in district court a final, individual determination that followed the approach described in the Framework. In that proceeding, Petitioner could make the same arguments it advances here, and assert that the SNUR approach is inconsistent with the requirements of TSCA. Thus, concluding that Petitioner lacks standing here does not prevent Petitioner from obtaining legal recourse.

II. NO SUBJECT-MATTER JURISDICTION EXISTS OVER THIS CHALLENGE BECAUSE THE FRAMEWORK IS A NON-FINAL POLICY STATEMENT.

A. The Framework Does Not Alter the Legal Regime, and so Is a Non-final Policy Statement.

As relevant here, judicial review is available under TSCA section 2618(a)(1)(A) only where the action at issue is a final rule.[4] An action is "final" if it meets two conditions: (1) the action must "mark the consummation of the agency's decisionmaking process," and (2) the action "must be one by which rights or obligations have been determined, or from which legal consequences will flow." *Paskar v. DOT*, 714 F.3d 90, 96 (2d Cir. 2013) (quoting *Bennett v. Spear*, 520 U.S. 154, 177-78 (1997)).[5]

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[4] Because jurisdiction exists under section 2618(a)(1)(A) only over certain final rules and orders, the finality question is jurisdictional in nature. *See, e.g.*, *Sierra Club*, 873 F.3d at 951 (examining analogous provision under the Clean Air Act and concluding "[i]n the absence of final agency action, we lack jurisdiction to hear an administrative challenge").

[5] *Paskar* considered whether the challenged action constituted a final order, not a final rule as here. *Id*. The finality inquiry, however, is the same for both rules and orders—the Court examines whether *Bennett*'s conditions are met. *See Bennett*, 520 U.S. at 177-78 (announcing test for determining whether agency action generally is "final").

On the second element, if the action does not "alter the legal regime" such that it "imposes an obligation," "denies a right," or "fixes some legal relationship," then the action is non-final for the purpose of judicial review. *Paskar*, 714 F.3d 96; *DRG Funding Corp. v. HUD*, 76 F.3d 1212, 1214 (D.C. Cir. 1996) (a nonfinal action is one, "for instance, that does not itself adversely affect complainant but only affects his rights adversely on the contingency of future administrative action") (citation omitted).

Where the action challenged is a guidance document, "the finality inquiry is often framed as the question of whether the challenged agency action is best understood as a non-binding action, like a policy statement or interpretive rule, or a binding legislative rule." *Ass'n of Flight Attendants-CWA, AFL-CIO v. Huerta*, 785 F.3d 710, 716 (D.C. Cir. 2015).[6] "Legislative rules have the force and effect of law and may

[6] Some decisions address the final agency action question separately from the legislative rule question. *See, e.g.*, *Gen. Elec. Co. v. EPA*, 290 F.3d 377, 380-82 (D.C. Cir. 2002). As *Huerta* explained, where the challenged conduct is characterized by the agency as a guidance document, the final agency action question and the legislative rule question essentially collapse into a single inquiry regarding the legal effect of the document at issue. 785 F.3d at 716; *see also Nat'l Mining*, 758 F.3d at 250-51 (similar).

be promulgated only after public notice and comment." *Nat'l Mining Ass'n v. McCarthy*, 758 F.3d 243, 250 (D.C. Cir. 2014).

A policy statement, on the other hand, "merely explains" the agency's interpretation of a statute or regulation, *id.*, leaving the agency the "discretion and the authority to change its position in any specific case." *Sierra Club*, 873 F.3d at 951; *accord Cruz-Miguel v. Holder*, 650 F.3d 189, 200 (2d Cir. 2011) ("internal guidance documents are not binding agency authority"). Notice and comment are not required for statements of policy, regardless of whether they announce a change in the agency's position. *Huerta*, 785 F.3d at 718 (*citing Perez v. Mortg. Bankers Ass'n*, 135 S. Ct. 1199, 1207 (2015)).[7]

To determine whether an agency action is a legislative rule or a policy statement, the Court looks to "the actual legal effect (or lack thereof) of the agency action in question" on regulated entities, and "how an agency has characterized a purported guidance." *Huerta*, 785

[7] Interpretive rules are those rules that "are issued by an agency to advise the public of the agency's construction of the statutes and rules which it administers." *Huerta*, 785 F.3d at 713 (citation omitted). A policy statement may interpret a statute or may not. *See id.* Either way, both interpretive rules and policy statements need not be issued through notice and comment, and "do not have the force and effect of law." *Id.*

F.3d at 717. The Court may also examine post-guidance events to determine whether the agency has applied the guidance "as if it were binding." *Nat'l Mining*, 758 F.3d at 253.

Applying these factors, *Sierra Club v. EPA*, held that a document setting forth EPA's "recommended methodology" for undertaking an analysis required by the Clean Air Act was a policy statement, and not a legislative rule. 873 F.3d 946. The court reasoned that the guidance did not have binding legal consequence because it "explicitly states that the EPA was open to considering better, alternative methods" different from the one set forth in the document. *Id.* at 951. Thus, "EPA's vow to remain flexible" established that the document "does not express a final agency action." *Id.* at 952-53.

Independent Equipment Dealers Ass'n v. EPA, 372 F.3d 420 (D.C. Cir. 2004) (Roberts, J.), reached the same conclusion regarding an EPA letter interpreting a regulation. The court considered a challenge to the letter, which described the agency's interpretation of a regulation governing the labeling of imported engines. *Id.* 425-26. The court held that the letter was not reviewable—it was "purely informational in nature; it imposed no obligations and denied no relief." *Id.* at 427.

"Compelling no one to do anything, the letter had no binding effect whatsoever—not on the agency and not on the regulated community." *Id*. Thus, the letter was not a legislative rule, but was instead a policy statement. *Id*. *See also Huerta*, 785 F.3d at 713-18 (guidance that set forth new "streamlined procedure" for aviation safety inspectors was not a legislative rule because it left "aviation safety inspectors free to consider the individual facts in the various cases that arise") (internal quotation marks and citation omitted).

By contrast, *Appalachian Power Co. v. EPA*, 208 F.3d 1015 (D.C. Cir. 2000), evaluated a guidance document that interpreted certain regulations to require state permitting authorities to include monitoring requirements in the permits they issued. *Id*. at 1023. The court held that it was a legislative rule because "[i]t commands, it requires, it orders, it dictates." *Id*. That the guidance created "obligations on the part of the State regulators and those they regulate" was dispositive of the court's analysis, even though the guidance included "boilerplate" language that it did not "represent final Agency action." *Id*.

1. The Framework does not create any new legally binding obligations.

Here, the Framework is not a final, legislative rule because it does not "alter the legal regime" established by TSCA, such that the Framework has legal consequences for EPA, or for regulated parties. *Paskar*, 714 F.3d at 96. The Framework does not purport to constrain or expand the agency's authority under section 5, 15 U.S.C. § 2604, to make determinations on pre-manufacture notices. It merely outlines a "working approach" the agency may take in determining that a chemical substance is "not likely to present unreasonable risk." Framework at 1, JA__. Specifically, "[w]here EPA has concerns with reasonably foreseen conditions of use, but not with the intended conditions of use described in a submission," the Agency "will assess whether those concerns can be addressed through significant new use rules." *Id.* at 2, JA__.

Thus, the Framework is akin to the document at issue in *Sierra Club*, which the court held was a policy statement because it did not constrain the agency's discretion in any particular case. The Framework, like the guidance there, "explicitly states" that the agency is "open to considering . . . alternative methods." 873 F.3d at 951. And,

the Framework further provides that the circumstances of an individual pre-manufacture notice may "warrant different from the one set forth in the document." Framework at 4, JA__. The purpose of the Framework is "purely informational in nature." *Indep. Equip. Dealers*, 372 F.3d at 427. "Compelling no one to do anything," *id.*, its only impact is on the "contingency of future administrative action"—namely, the issuance of a determination on a pre-manufacture notice at some later date that follows the approach described in the guidance. *DRG Funding Corp.*, 76 F.3d at 1214 (internal quotation marks and citation omitted).

Contrary to Intervenor's contentions, the Framework is nothing like the guidance document at issue in *Appalachian Power*, which was binding on agency officials. That document included uncompromising language, thus creating legal consequences for the regulators and regulated parties; "[i]t commands, it requires, it orders, it dictates." 208 F.3d at 1023-24. (Intv. Br. at 25-26.) Nor is the Framework analogous to the document at issue in *Natural Resources Defense Council v. EPA*, 643 F.3d 311 (D.C. Cir. 2011). (Pet. Br. at 45-49, Intv. Br. at 26.) The guidance there had clear legal effect because it definitively eliminated the discretion of certain state actors that existed before it was issued.

643 F.3d at 319–20. The Framework, by contrast, states that it does not constrain the agency's discretion.[8] It is thus not binding, and not a legislative rule. *Sierra Club*, 873 F.3d at 951.

2. EPA's characterization of the Framework makes clear that it is a statement of policy.

EPA's characterization of the Framework shows that it is a policy statement, and not a legislative rule. The Framework expressly states that it articulates the Agency's "working approach," that it is "not intended to be interpretations of what is required by TSCA or the range of discretion afforded by TSCA," and is intended merely to "outline EPA's approach to making decisions on new chemical notices submitted to EPA under TSCA section 5." Framework at 1, 3, JA__, __. In addition, as discussed above, EPA made clear that the Framework does not constrain the Agency's discretion in any particular case, stating that circumstances may "warrant different approaches from those set out here." *Id.* at 3, JA__.

[8] The letter at issue in *Iowa League of Cities v. EPA*, 711 F.3d 844 (8th Cir. 2013), is also distinguishable. (Intv. Br. at 29.) Unlike the Framework, which makes clear that the Agency will engage in a case-by-case determination, the court in that case found the letter spoke in "mandatory terms" such as "should not be permitted" and was binding in practice. 711 F.3d at 863-65.

These statements are not mere "boilerplate" recited on the first page of the document. *See Appalachian Power Co.*, 208 F.3d at 1023. They are included throughout, and are not contradicted elsewhere by the text. Further, EPA did not publish the Framework in the Code of Federal Regulations which indicates that the Agency did not intend the Framework as a binding rule. *See The Wilderness Soc'y v. Norton*, 434 F.3d 584, 595–96 (D.C. Cir. 2006) (stating that the Code of Federal Regulations contains "each Federal regulation of general applicability and current or future effect") (internal quotation marks and citation omitted). Rather, it sought comments on the Framework, which it labeled as a "draft," in a Federal Register notice. 82 Fed. Reg. 51,415. EPA is continuing to consider these comments (Decl. ¶ 7), and may make changes in response. These factors all indicate that EPA intended the Framework to be a mere statement of policy, not a final rule.

Dr. Morris's comments at the public meeting on December 6, 2017 do not show otherwise. Dr. Morris explained the Agency's view at that time that "reasonably foreseen uses" could be addressed by issuing a significant new use rule. Tr. at 4, JA__. Then, "if anyone wants to deviate from the conditions described in the pre-manufacture notice, for

which we don't have concerns," they would have to file a significant new use notice "so we can evaluate . . . whether or not [that new use] presents an issue." *Id.* It is true that Dr. Morris stated that "we are acting on the Framework and governing ourselves by the framework." *Id.* But, elsewhere he said that "this is an area of active discussion" for which he welcomes input, and that he "fully expect[s] that as we take comments . . . how we describe things will change a bit." Tr. at 7, 10, JA__, __. Dr. Morris also said that using a significant new use rule to address reasonably foreseen uses was not automatic: "*should* we go the SNUR route in a particular case," then the Agency will "want to make sure [it is] very clear on how it links to what is outlined in the PMN." Tr. at 11, JA__. It is also worth noting that Dr. Morris's comments about the Framework at this meeting were not scripted remarks, but part of a free-form question and answer session, and so hardly reflect a definitive pronouncement on the Framework's legal effect. *See id.*

Thus, EPA's characterization of the Framework shows that it is intended as a policy statement, not a final legislative rule.

3. EPA's treatment of the Framework confirms that it is not legally binding.

Lastly, EPA's treatment of the Framework confirms that it has no legal consequence, and is not binding on the Agency. Since the Framework's issuance in 2017, EPA has made 150 determinations on pre-manufacture notices. (Decl. ¶ 9.) Of these, the Agency has concluded that 19 chemical substances were "not likely to present an unreasonable risk of injury to health or the environment" under those substances' "conditions of use," 15 U.S.C. § 2604(a)(3)(C). (Decl. ¶ 10.) For none of those determinations did EPA follow the significant new use rule approach described in the Framework.

In addition, with regard to 131 pre-manufacturer notices, the agency made a determination under section 5(a)(3)(B), § 2604(a)(3)(B), related to the lack of sufficient information. (Decl. ¶ 11.) The Agency then addressed its concerns by, among other things, issuing orders under section 2604(e). (*Id.*) EPA did not, in any of these cases, apply the approach described in the Framework. (*Id.*) This is true even though a significant number of these determinations related to the reasonably foreseen conditions of use for the new chemical substance at issue. (*Id.*)

EPA simply has not applied the Framework as though it were legally binding on the agency, or on any regulated party.

Because the Framework is a policy statement and not a final rule, this dispute is necessarily not ripe for review. The Framework "does not carry the force of law" and so Petitioner will "suffer no legally cognizable hardship" from this Court withholding review now. *Am. Tort Reform Ass'n v. OSHA*, 738 F.3d 387, 407 (D.C. Cir. 2013). The Supreme Court held that where an agency's interpretative guideline "does not have 'adverse effects of a strictly legal kind'"—i.e., where the document is a policy statement and not a legislative rule, subject-matter jurisdiction is lacking. *Nat'l Park Hosp. Ass'n v. DOI*, 538 U.S. 803, 809 (2003) (citation omitted). Indeed, Petitioner's and Intervenor's arguments regarding ripeness are all premised on the (incorrect) assumption that the Framework is a legislative rule. (Pet. Br. at 26-29; Intv. Br. at 30-36.) It is not, and so subject-matter jurisdiction is lacking here for this reason as well.

B. The Varied Attempts to Characterize the Framework as a Legislative Rule Are All Meritless.

Petitioner and Intervenor assert that the Framework is a legislative rule for two reasons, neither of which has merit.

First, Petitioner and Intervenor argue that the Framework must have legal consequence, and accordingly be considered a final, legislative rule. They claim it authorizes a procedure that purportedly "departs from the governing statute," and so creates a binding change in the law that will necessarily control individual determinations. (Pet. Br. at 44-47; Intv. Br. at 29.) But, as discussed above, the Framework makes clear that it is not a new source of authority. It describes only EPA's present understanding of the "general principles for making section 5 determinations and some of the factors considered" as provided by the Act. Framework at 3, JA__. The statutory provisions of TSCA—not the Framework—provide EPA authority to evaluate whether a new chemical substance is "not likely to present an unreasonable risk" under its "conditions of use," 15 U.S.C. § 2604.

EPA's practice confirms that the Framework has not controlled individual determinations. EPA expressed its intention to adapt its draft approach as appropriate in response to those comments and additional agency experience and analysis. *See supra* at 13-14. Indeed, EPA has not yet applied the approach described in the Framework, instead applying other approaches. *See supra* at 14-15.

Second, Petitioner asserts that the Framework cannot be a policy statement regarding the Agency's interpretation of section 5 of TSCA, 15 U.S.C. § 2604, because the "pre-manufacture review process for new chemicals . . . is not a discretionary power of EPA." (Pet. Br. at 47.) By this, it appears Petitioner is arguing that the application of section 2604's requirements does not involve any discretionary judgments by EPA, and so the Agency cannot discuss how it may exercise this discretion in a policy statement.

But, consideration of whether a new chemical substance is likely to present unreasonable risk of injury to health or the environment requires the Administrator to exercise his judgment based on the facts and circumstances of an individual case. The Administrator's evaluation thus properly includes discretionary judgments, including determining the risk posed by a new chemical substance, and the "conditions of use" for the substance. § 2602(4) (defining "conditions of use" as the "circumstances, as determined by the Administrator, under which the chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of"); § 2604(a) (assigning to the Administrator the duty to

make a determination). *See also infra* at 44-49. That EPA must make a determination regarding each pre-manufacture notice, and follow the requirements of TSCA while so doing, plainly does not foreclose the Agency from exercising discretion where permitted as part of this process.

C. EPA's Release of the Framework Was Procedurally Proper.

Because, as discussed *supra* at 28-39, the Framework is a policy statement and not a final, legislative rule, EPA's issuance of the Framework without first completing in notice and comment rulemaking was procedurally proper. *See Huerta*, 785 F.3d at 718. Petitioner and Intervenor have cited no authority to the contrary and there is none. (Pet. Br. at 26; Intv. Br. at 35.)

D. The Application of the Framework to an Individual Pre-manufacture Notice May Be Challenged.

EPA concedes that even though the Framework is not final agency action, that does not insulate specific determinations that may apply the Framework's principles from challenges—should EPA ever apply those principles. A person may challenge in district court a determination that a new chemical substance is "not likely to present

unreasonable risk of injury to health or the environment" under "its conditions of use" pursuant to 15 U.S.C. § 2604(a)(3). This determination would constitute "final agency action" that may be reviewed pursuant to the Administrative Procedure Act, 5 U.S.C. § 704, as long as the plaintiff in that case had standing.

Indeed, Intervenor concedes as much. It notes that its members could possibly seek redress by "district court challenges to individual 'not likely' determinations." (Intv. Br. at 34.) Intervenor complains that such suits could "pose standing and other hurdles." (*Id.*) Intervenor's concern that it may not have standing to challenge individual determinations on a specific chemical substance does not provide a reason to allow this challenge to proceed. Rather, its acknowledgement directly undermines Petitioner's assertion that it has standing here. *See supra* at 23-27.

To be clear, because the Framework is not a legislative rule, EPA may not rely on the Framework as a source of authority in issuing a determination on a pre-manufacture notice. Thus, in the context of a challenge to an individual determination, agency policy statements like the Framework may provide some additional useful context and

explanation of the basis for the agency's decision. But, at the end of the day the court's legal analysis would examine only whether the determination is consistent with the requirements of TSCA and EPA's implementing regulations—not whether the approach is consistent with the Framework.

III. THE FRAMEWORK IS CONSISTENT WITH THE REQUIREMENTS OF TSCA SECTION 5.

The approach described in the Framework is consistent with TSCA section 5, § 2604. The Act affords EPA discretion to make any determination regarding a pre-manufacture notice that is supported by the facts of that case. Separately, significant new use rules are one tool the Act provides to address concerns with chemical substances. EPA might rationally conclude, as part of its evaluation of a pre-manufacture notice, that a new chemical substance will not present unreasonable risk under its conditions of use where certain uses of that substance have been addressed through a significant new use rule. Petitioner's arguments that this approach is facially unlawful are unavailing.

A. EPA's Approach Is Reasonable.

TSCA section 5, 15 U.S.C. § 2604, requires EPA to make a determination on each pre-manufacture notice submitted. The Act

provides that EPA must make one of the determinations prescribed by the statute, § 2604(a)(1)(B)(ii)(II). EPA may conclude the chemical substance presents an "unreasonable risk of injury to health or the environment" under its "conditions of use." § 2604(a)(3)(A); that the "information available" is insufficient "to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance," § 2604(a)(3)(B)(i); that the chemical substance is "not likely to present an unreasonable risk of injury to health or the environment" under its "conditions of use," § 2604(a)(3)(C), among others.

The phrase "conditions of use" is defined by the Act to include "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." § 2602(4).

EPA's assessment of which determination is appropriate in any individual case requires a fact-specific inquiry. The agency must exercise its judgment, and determine both the risk posed by the new chemical substance, as well as the conditions of use of that substance. Because the possible determinations prescribed by the Act could overlap

in some respects, the statute affords EPA discretion to choose any appropriate finding. *See* § 2604(a). Section 5, § 2604, requires only that EPA make a supported determination—it does not dictate which determination the Agency must reach in each case.

In addition, TSCA allows EPA to address new uses of chemical substances as necessary to protect public health and the environment through the promulgation of "significant new use rules." § 2604(a)(2). Once a significant new use rule is issued, a person may not manufacture or process the chemical substance in the manner proscribed by the significant new use rule without first obtaining approval to do so from EPA. § 2604(a)(1)(A)(ii). To obtain approval, a person must submit a significant new use notice to the agency. *Id.* EPA then makes a determination on the significant new use notice following the same procedure that applies to evaluation of pre-manufacture notices. § 2604(e). *Id.*

The Framework, in turn, outlines one approach EPA may follow in determining that a new chemical substance is "not likely to present an unreasonable risk of injury to health or the environment" under its "conditions of use." § 2604(a)(3)(C). The agency may, in an appropriate

case, take into account whether "concerns regarding the conditions of use" had been adequately addressed through "issuance of a SNUR." Framework at 4, JA__. In sum, it may be a rational exercise of the Administrator's discretion, in an appropriate case, to conclude that it is not likely that a new chemical substance will present unreasonable risk where certain uses of that substance are otherwise addressed by a significant new use rule. That is so because a person cannot lawfully manufacture the substance for that use, unless and until that person seeks permission from EPA to do so pursuant to section 2403(a)(1), and EPA makes a determination regarding the risk of the new use.

Relatedly, the issuance of a significant new use rule could also affect the "conditions of use" of a new chemical substance. Again, the Act defines "conditions of use" to include those circumstances "as determined by the Administrator" that a chemical substance is "reasonably foreseen" to be manufactured or used. § 2602(4). EPA might rationally conclude that where a significant new use rule presently proscribes a use, it is not reasonably foreseen that a chemical substance will be manufactured or used in that manner. *Id.*

That the Administrator has discretion to make appropriate judgments on the facts of a specific case is made clear by the statutory language that assigns to the Administrator the duty to make determinations on unreasonable risk and also the conditions of use. *See* § 2604(a)(3) (requiring the Administrator to make a determination); § 2602(4) (defining "conditions of use" as "the circumstances, *as determined by the Administrator*, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of") (emphasis added).

The phrase "as determined by the Administrator" plainly indicates that Congress intended to "give[ ] the EPA administrator discretion" to make a factual finding based on the evidence before the Agency. *Nat. Res. Def. Council v. EPA*, 526 F.3d 591, 595 n.4 (9th Cir. 2008) (conference report stating that permits are not required where runoff is not contaminated "as determined by the Administrator" "gives the EPA administrator discretion to determine when contamination has occurred" (internal quotation marks and citation omitted)); *see also Transitional Hosps. Corp. of La. v. Shalala*, 222 F.3d 1019, 1025, 1026 (D.C. Cir. 2000) (By using the "parenthetical phrase, 'as determined by

the Secretary' . . . Congress has made an express delegation of authority to the agency" that "takes the case out of the realm of *Chevron* step one[]") (citation omitted). For our purposes, the use of this phrase means that EPA has discretion to determine the risk posed by the substance, and what, precisely, are the circumstances under which a chemical is reasonably foreseen to be used such that it constitutes a "condition of use."

Petitioner and Intervenor raise two arguments regarding this construction of section 5, § 2604. *First*, they contend that the Framework's approach is unlawful because TSCA dictates that the agency take a specific action with regards to each pre-manufacture notice, and that none of these specific actions include the promulgation of a significant new use rule. (Pet. Br. at 13, 30; Intv. Br. at 20, 21). This argument, however, does not grapple with the statutory language conferring discretion on the Administrator to make a determination.

Second, Petitioner and Intervenor assert that EPA lacks authority under TSCA to issue a significant new use rule before EPA has completed review of the pre-manufacture notice. (Pet. Br. at 32; Intv. Br. at 47.) This argument also fails. The plain language of section

2604(a)(2) confers broad authority on the Administrator to determine that "use of a chemical substance is a significant new use" and then issue a significant new use rule, without limitation to whether the chemical substance has undergone review under section 2604(a)(3) or any other TSCA authority.

B. The Framework's Approach Takes into Account All of a Substance's Conditions of Use.

Next, Petitioner and Intervenor argue that the Framework's approach is inconsistent with the purpose of section 5, § 2604, and improperly truncates EPA's review of a new chemical substance. They claim the Framework's approach allows the agency to examine only whether a chemical substance poses risk under its "intended conditions of use," instead of reasonably foreseen conditions of use. (Pet. Br. at 3, 20, 24, 44; Intv. Br. at 41.) This is incorrect. EPA is not constraining its evaluation of a chemical substance to only those intended conditions of use identified in the pre-manufacture notice. Rather, the Framework describes a process where EPA examines all reasonably foreseen conditions of use and takes into account whether a use requires prior

approval by EPA in determining whether it poses unreasonable risk. *See supra* at 44-47. This approach is permissible under the Act.[9]

C. Petitioner and Intervenor's Arguments Misunderstand the Legal Effect of Significant New Use Rules.

Petitioner and Intervenor also assert that the Framework is inconsistent with TSCA section 5, 15 U.S.C. § 2604, because issuing a significant new use rule concurrently with a determination is not as protective as a consent order. (*E.g.*, Pet. Br. at 3, 37-42; Intv. Br. at 23, 29, 38, 46, 50.) As examples, they contend that EPA has no way of knowing whether a chemical substance is being used in the manner prohibited (Pet. Br. at 42), and a significant new use rule cannot protect against harmful exposure to workers (*Id.* at 40; Intv. Br. at 29).

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[9] To the extent that Intervenor challenges the aspect of the Framework that describes how EPA may consider a manufacturer's amendment to a pre-manufacture notice, this argument is not properly before the Court. (*See* Intv. Br. at 39-40.) Petitioner does not advance this argument, and it is well established that an intervenor may not raise arguments not raised by a principal party. *See N.Y. Dep't of Envtl. Conservation v. FERC*, 884 F.3d 450, 456 (2d Cir. 2018). In any event, Intervenor's concern that allowing an amendment to a pre-manufacture notice may curtail EPA's review of the conditions of use is misguided. Any determination EPA makes in an individual case must be consistent with the requirements of section 2604, and supported on the facts of that case. *See supra* at 44-47.

Petitioner and Intervenor misunderstand the legal effect of a significant new use rule. A significant new use rule prohibits the manufacture or processing of a chemical substance for the significant new use identified in the rule absent further action by EPA pursuant to a significant new use notice. § 2604(e). In other words, a significant new use rule can have an equivalent (or even greater) practical effect as an order. The use of a chemical substance in a manner addressed by a significant new use rule is unlawful, just like use of a chemical substance in a manner prohibited by an order is unlawful.

Indeed, both before and after the 2016 Amendments, orders issued under section 2604(e) & (f) govern the pre-manufacture notice submitter alone, and no one else. Accordingly, to prevent a person other than the submitter from using a chemical in a manner prohibited by a section 2604 order, a significant new use rule is typically necessary. Thus, a significant new use rule can provide even greater protection than an order standing alone, because a significant new use rule applies to both the submitter as well as other parties.

Indeed, the Act specifically instructs that whenever EPA has issued an order under sections 2604(f) or 2604(e), the Agency must then

within ninety days "consider whether to promulgate" a significant new use rule. § 2604(f)(4). EPA evaluates whether it should identify as a "significant new use" the use of the chemical substance in a manner "that does not conform to the restrictions imposed by" the earlier issued order under section 2604(f) or (e). *Id*. Plainly, Congress viewed significant new use rules as replicating the restrictions imposed by orders.

Petitioner's arguments regarding the inability for significant new use rules to address worker safety also fall flat. The regulations implementing section 2604 make clear that significant new use rules may address worker safety. *E.g.*, 40 C.F.R. § 721.63 (addressing use of SNURs for "protection in the workplace"); § 721.72 (similar). Thus, significant new use rules are one vehicle EPA had prior to the 2016 Amendments, and still has, to address unreasonable risk which are effective as section 5, § 2604, orders.[10]

[10] The arguments that significant new use rule may not be adequately protective in a particular case because there may be inadequate information about a particular new chemical substance, or that the significant new use rule may not be timely issued is entirely speculative. (Intv. Br. at 23, 43, 49.) Again, if Petitioner or Intervenor believe that EPA's determination as to a particular pre-manufacture

CONCLUSION

For the reasons described above, the petition for review should be dismissed.

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notice is unsupported, they can challenge that determination. *See supra* at 42-44.

Similarly, that the Act does not mandate that significant new use rules provide a "prescribed level of protection" is irrelevant. (Intv. Br. at 50-51.) A determination that relies on a significant new use rule which does not adequately address risk concerns would make the determination subject to challenge. It does not make the Framework's approach facially flawed.

Respectfully submitted,

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July 31, 2018

CERTIFICATE OF COMPLIANCE WITH FEDERAL RULE 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 Century Schoolbook, a proportionally spaced font.

I further certify that this brief complies with the type-volume limitation of Fed. R. App. P. 32(a)(7)(B) because it contains 10,569 words, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

/s/ *Meghan E. Greenfield*
MEGHAN E. GREENFIELD

CERTIFICATE OF SERVICE

I hereby certify that on July 31, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the Second Circuit by using the appellate CM/ECF system.

The participants in the case are registered CM/ECF users and service will be accomplished by the appellate CM/ECF system.

/s/ Meghan E. Greenfield
MEGHAN E. GREENFIELD

EXHIBIT A

STANDING ADDENDUM

IN THE UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

NATURAL RESOURCES DEFENSE COUNCIL,	)	
Petitioners,	)	
v.	)	No. 18-25
UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,	)	
Respondents.	)	

DECLARATION OF JEFFERY MORRIS

I, Jeffery Morris, state the following:

1. I declare that the following statements are true and correct to the best of my knowledge and belief and are based upon my personal knowledge and/or on my review of information contained in the records of the United States Environmental Protection Agency ("EPA" or "Agency") or supplied by current employees.

2. I am the director of EPA's Office of Pollution Prevention and Toxics ("OPPT"). I became OPPT director in 2016, having, served as OPPT's Deputy Director for Programs from 2011 to 2016.

3. OPPT is the office assigned with the responsibility of regulating chemicals under the Toxic Substances Control Act ("TSCA"), including issuing determinations regarding Premanufacture Notices ("PMNs") under TSCA Section 5(a)(3).

4. This declaration is filed in support of EPA's response brief in the above captioned case.

5. In reviewing PMNs under TSCA, EPA makes a determination under Section 5(a)(3). These determinations are issued either by the OCSPP Principal Deputy Assistant Administrator based on the work of persons under my supervision, by me, or by persons under my supervision with delegated authority.

6. On November 7, 2017, in conjunction with the public meeting to be held on December 6, 2017, EPA published for comment a document entitled "New Chemicals Decision-Making Framework: *Working Approach to Making Determinations under Section 5 of TSCA*" (Framework).

7. The agency is continuing to consider those comments submitted in response to the Framework.

8. Among the topics discussed in the Framework is the ability to consider Significant New Use Rules (SNURs) under TSCA Section 5(a)(2) when issuing Section 5(a)(3) determinations, including "not likely to present an unreasonable risk" determinations under Section 5(a)(3)(C).

9. EPA considers the "conditions of use" of the PMN when making determinations under Section 5(a)(3). Under Section 3(4) the term "conditions of use" means "the circumstances, as determined by the Administrator, under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of." Since November 6, 2017 EPA has issued 150 Section 5(a)(3) determinations regarding PMNs.

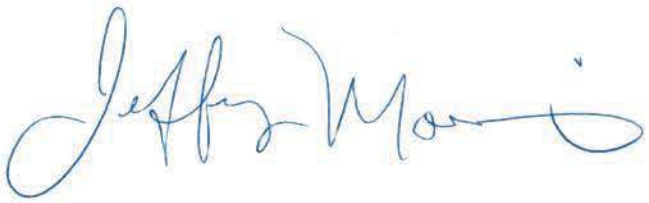
10. With respect to 19 of the PMNs referred to in Paragraph 9, EPA determined that the PMN substance is not likely to present an unreasonable risk under Section 5(a)(3)(C). In none of these determinations did EPA consider a SNUR as a factor in determining that unreasonable risk was unlikely.

11. With respect to the remainder of the PMNs referred to in Paragraph 9 (131 PMNs), EPA made a determinations under either

Section 5(a)(3)(B)(i) (insufficient information to permit a reasoned evaluation) or Section 5(a)(3)(B)(ii(I)) (in the absence of sufficient information the PMN substance may present an unreasonable risk of injury to health and the environment). As required by Section 5(a)(3)(B), these determinations were followed by an order under Section 5(e). With respect to a significant number of these determinations, the basis for the Section 5(a)(3)(B) determination related to reasonably foreseen conditions of use of the PMN substance, rather than to known or intended conditions of use as described in the PMN.

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 the 31st day of July 2018.



Jeffery Morris

STATUTORY AND REGULATORY ADDENDUM

STATUTORY AND REGULATORY ADDENDUM

TABLE OF CONTENTS

Except for the following, all applicable Statutes and Code of Federal Regulations, are contained in Petitioner's Addendum.

FEDERAL REGULATIONS

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 721. Significant New Uses of Chemical Substances (Refs & Annos)
Subpart B. Certain Significant New Uses (Refs & Annos)

40 C.F.R. § 721.63

§ 721.63 Protection in the workplace.

Currentness

(a) Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of the substance is any manner or method of manufacturing, importing, or processing associated with any use of the substance without establishing a program whereby:

(1) Each person who is reasonably likely to be dermally exposed in the work area to the chemical substance through direct handling of the substance or through contact with equipment on which the substance may exist, or because the substance becomes airborne in the form listed in paragraph (a)(6) of this section, and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, personal protective equipment that provides a barrier to prevent dermal exposure to the substance in the specific work area where it is selected for use. Each such item of personal protective equipment must be selected and used in accordance with 29 CFR 1910.132 and 1910.133.

(2) In addition to any other personal protective equipment selected in paragraph (a)(1) of this section, the following items are required:

(i) Gloves.

(ii) Full body chemical protective clothing.

(iii) Chemical goggles or equivalent eye protection.

(iv) Clothing which covers any other exposed areas of the arms, legs, and torso. Clothing provided under this paragraph need not be tested or evaluated under the requirements of paragraph (a)(3) of this section.

(3) The employer is able to demonstrate that each item of chemical protective clothing, including gloves, selected provides an impervious barrier to prevent dermal exposure during normal and expected duration and conditions of exposure within the work area by any one or a combination of the following:

(i) Testing the material used to make the chemical protective clothing and the construction of the clothing to establish that the protective clothing will be impervious for the expected duration and conditions of exposure. The testing must

subject the chemical protective clothing to the expected conditions of exposure, including the likely combinations of chemical substances to which the clothing may be exposed in the work area.

(ii) Evaluating the specifications from the manufacturer or supplier of the chemical protective clothing, or of the material used in construction of the clothing, to establish that the chemical protective clothing will be impervious to the chemical substance alone and in likely combination with other chemical substances in the work area.

(4) Each person who is reasonably likely to be exposed to the chemical substance by inhalation in the work area in one or more of the forms listed in paragraph (a)(6) of this section and cited in subpart E of this part for the chemical substance, is provided with, and is required to wear, at a minimum, a NIOSH- approved respirator from one of the categories listed in paragraph (a)(5) of this section, and the respirator is used in accordance with 29 CFR 1910.134 and 30 CFR part 11.

(5) The following NIOSH approved respirators meet the minimum requirements for paragraph (a)(4) of this section:

(i) Category 19C Type C supplied-air respirator operated in pressure demand or other positive pressure mode and equipped with a full facepiece.

(ii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a tight-fitting facepiece.

(iii) Category 19C Type C supplied-air respirator operated in pressure demand or continuous flow mode and equipped with a hood or helmet or tight-fitting facepiece.

(iv) Category 21C air-purifying respirator equipped with a full facepiece and high efficiency particulate filters.

(v) Category 21C powered air-purifying respirator equipped with a tight-fitting facepiece and high efficiency particulate filters.

(vi) Category 21C powered air-purifying respirator equipped with a loose-fitting hood or helmet and high efficiency particulate filters.

(vii) Category 21C air-purifying respirator equipped with a high efficiency particulate filter including disposable respirators.

(viii) Category 23C air-purifying respirator equipped with a full facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(ix) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(x) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and combination cartridges approved for paints, lacquers, and enamels. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xi) Category 23C air-purifying respirator equipped with combination cartridges approved for paints, lacquers, and enamels, including disposable respirators. (Approval label may preclude use for some paints, lacquers, or enamels.)

(xii) Category 23C air-purifying respirator equipped with a full facepiece and organic gas/vapor cartridges.

(xiii) Category 23C powered air-purifying respirator equipped with a tight-fitting facepiece and organic gas/vapor cartridges.

(xiv) Category 23C powered air-purifying respirator equipped with a loose-fitting hood or helmet and organic gas/vapor cartridges.

(xv) Category 23C air-purifying respirator equipped with organic gas/vapor cartridges, including disposable respirators.

(6) When cited in subpart E of this part for a substance, the following airborne form(s) of the substance apply to paragraphs (a)(1) and (4) of this section:

(i) Dust.

(ii) Mist.

(iii) Fume.

(iv) Smoke.

(v) Vapor.

(vi) Gas.

(b) If a substance identified in subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in subpart E of this part.

(c)(1) If at any time after commencing distribution in commerce of a chemical substance that is identified in subpart E of this part as subject to this section, the person has knowledge that a recipient of the substance is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, the person is considered to have knowledge that the recipient is engaging in a significant new use and is required to follow the procedures in § 721.5(d) unless the person is able to document the following:

(i) That the person has notified the recipient in writing within 15 working days of the time the person first has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section, and that the person has knowledge of the failure of implementation.

(ii) That within 15 working days of notifying the recipient that the recipient is engaging in an activity that is not consistent with the implementation of a program specified in paragraph (a) of this section the person has received from the recipient, in writing, a statement of assurance that the recipient has established the program required under paragraph (a) of this section, and will take appropriate measures to avoid activities that are inconsistent with implementation of the program required under paragraph (a) of this section.

(2) If, after receiving a statement of assurance from a recipient under paragraph (c)(1)(ii) of this section, a manufacturer, importer, or processor has knowledge that the recipient is engaging in an activity that is not consistent with the implementation of the program specified in paragraph (a) of this section, that person is considered to have knowledge that the person is engaging in a significant new use and is required to follow the procedures in § 721.5(d).

AUTHORITY: 15 U.S.C. 2604, 2607, and 2625(c).

Current through July 20, 2018; 83 FR 34497

End of Document

Code of Federal Regulations
Title 40. Protection of Environment
Chapter I. Environmental Protection Agency (Refs & Annos)
Subchapter R. Toxic Substances Control Act
Part 721. Significant New Uses of Chemical Substances (Refs & Annos)
Subpart B. Certain Significant New Uses (Refs & Annos)

40 C.F.R. § 721.72

§ 721.72 Hazard communication program.

Currentness

Whenever a substance is identified in subpart E of this part as being subject to this section, a significant new use of that substance is any manner or method of manufacture, import, or processing associated with any use of that substance without establishing a hazard communication program as described in this section.

(a) Written hazard communication program. Each employer shall develop and implement a written hazard communication program for the substance in each workplace. The written program will, at a minimum, describe how the requirements of this section for labels, MSDSs, and other forms of warning material will be satisfied. The employer must make the written hazard communication program available, upon request, to all employees, contractor employees, and their designated representatives. The employer may rely on an existing hazard communication program, including an existing program established under the Occupational Health and Safety Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), to comply with this paragraph provided that the existing hazard communication program satisfies the requirements of this paragraph. The written program shall include the following:

(1) A list of each substance identified in subpart E of this part as subject to this section known to be present in the work area. The list must be maintained in the work area and must use the identity provided on the appropriate MSDS for each substance required under paragraph (c) of this section. The list may be compiled for the workplace or for individual work areas.

(2) The methods the employer will use to inform employees of the hazards of non-routine tasks involving the substance, for example, the cleaning of reactor vessels, and the hazards associated with the substance contained in unlabeled pipes in their work area.

(3) The methods the employer will use to inform contractors of the presence of the substance in the employer's workplace and of the provisions of this part applicable to the substance if employees of the contractor work in the employer's workplace and are reasonably likely to be exposed to the substance while in the employer's workplace.

(b) Labeling.

(1) Each employer shall ensure that each container of the substance in the workplace is labeled in accordance with this paragraph (b)(1).

(i) The label shall, at a minimum, contain the following information:

(A) A statement of health hazard(s) and precautionary measure(s) for the substance, if any, identified in subpart E of this part or by the employer.

(B) The identity by which the substance may be commonly recognized.

(C) A statement of environmental hazard(s) and precautionary measure(s) for the substance, if any, identified in subpart E of this part or by the employer.

(D) A statement of exposure and precautionary measure(s), if any, identified in subpart E of this part or by the employer.

(ii) The employer may use signs, placards, process sheets, batch tickets, operating procedures, or other such written materials in lieu of affixing labels to individual stationary process containers, as long as the alternative method identifies the containers to which it is applicable and conveys information specified by paragraph (b)(1)(i) of this section. Any written materials must be readily accessible to the employees in their work areas throughout each work shift.

(iii) The employer need not label portable containers into which the substance is transferred from labeled containers, and which are intended only for the immediate use of the employee who performs the transfer.

(iv) The employer shall not remove or deface an existing label on incoming containers of the substance unless the container is immediately relabeled with the information specified in paragraph (b)(1)(i) of this section.

(2) Each employer shall ensure that each container of the substance leaving its workplace for distribution in commerce is labeled in accordance with this paragraph.

(i) The label shall, at a minimum, contain the following information:

(A) The information required under paragraph (b)(1)(i) of this section.

(B) The name and address of the manufacturer or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(ii) The label shall not conflict with the requirements of the Hazardous Materials Transportation Act (18 U.S.C. 1801 et. seq.) and regulations issued under that Act by the Department of Transportation.

(3) The label, or alternative forms of warning, shall be legible and prominently displayed.

(4) The label, or alternative forms of warning, shall be in English; however, the information may be repeated in other languages.

(5) If the label or alternative form of warning is to be applied to a mixture containing a substance identified in subpart E of this part as subject to this section in combination with another substance identified in subpart E of this part and/or a substance defined as a "hazardous chemical" under the Occupational Safety and Health Administration (OSHA) Hazard Communication Standard (29 CFR 1900.1200), the employer may prescribe on the label, MSDS, or alternative form of warning, the measures to control worker exposure or environmental release which the employer determines provide the greatest degree of protection. However, should these control measures differ from the applicable measures required under subpart E of this part, the employer must seek a determination of equivalency for such alternative control measures pursuant to § 721.30 before prescribing them under this paragraph.

(c) Material safety data sheets.

(1) Each employer must obtain or develop a MSDS for the substance.

(2) Each MSDS shall contain, at a minimum, the following information:

(i) The identity used on the container label of the substance under this section, and, if not claimed confidential, the chemical and common name of the substance. If the chemical and common name are claimed confidential, a generic chemical name must be used.

(ii) Physical and chemical characteristics of the substance known to the employer (such as vapor pressure, flash point).

(iii) The physical hazards of the substance known to the employer, including the potential for fire, explosion, and reactivity.

(iv) The potential human and environmental hazards as specified in subpart E of this part for the substance.

(v) Signs and symptoms of exposure, and any medical conditions which are expected to be aggravated by exposure to the substance known to the employer.

(vi) The primary routes of exposure to the substance.

(vii) Precautionary measures to control worker exposure and/or environmental release identified in subpart E of this part for the substance, or alternative control measures which EPA has determined under § 721.30 provide substantially the same degree of protection as the identified control measures.

(viii) Any generally applicable precautions for safe handling and use of the substance which are known to the employer, including appropriate hygienic practices, protective measures during repair and maintenance of contaminated equipment, and procedures for response to spills and leaks.

(ix) Any generally applicable control measures which are known to the employer, such as appropriate engineering controls, work practices, or personal protective equipment.

(x) Emergency first aid procedures known to the employer.

(xi) The date of preparation of the MSDS or of its last revision.

(xii) The name, address, and telephone number of the individual preparing or distributing the MSDS, or a responsible party who can provide additional information on the substance for hazard evaluation and any appropriate emergency procedures.

(3) If no relevant information is found or known for any given category on the MSDS, the employer must mark the MSDS to indicate that no applicable information was found.

(4) Where multiple mixtures containing the substance have similar compositions (i.e., the chemical ingredients are essentially the same, but the specific composition varies from mixture to mixture) and similar hazards, the employer may prepare one MSDS to apply to all of these multiple mixtures.

(5) If the employer becomes aware of any significant new information regarding the hazards of the substance or ways to protect against the hazards, this new information must be added to the MSDS within 3 months from the time the employer becomes aware of the new information. If the substance is not currently being manufactured, imported, processed, or used in the employer's workplace, the employer must add the new information to the MSDS before the substance is reintroduced into the workplace.

(6) The employer must ensure that persons receiving the substance from the employer are provided an appropriate MSDS with their initial shipment and with the first shipment after an MSDS is revised. The employer may either provide the MSDS with the shipped containers or send it to the person prior to or at the time of shipment.

(7) The employer must maintain a copy of the MSDS in its workplace, and must ensure that it is readily accessible during each work shift to employees when they are in their work areas.

(8) The MSDS may be kept in any form, including as operating procedures, and may be designed to cover groups of substances in a work area where it may be more appropriate to address the potential hazards of a process rather than individual substances. However, in all cases, the required information must be provided for each substance and must be readily accessible during each work shift to employees when they are in their work areas.

(9) The MSDS must be printed in English; however, the information may be repeated in other languages.

(d) Employee information and training. Each employer must ensure that employees are provided with information and training on the substance identified in subpart E of this part. This information and training must be provided at the time of each employee's initial assignment to a work area containing the substance and whenever the substance subject to this section is introduced into the employee's work area for the first time.

(1) Information provided to employees under this paragraph shall include:

(i) The requirements of this section.

(ii) Any operations in the work area where the substance is present.

(iii) The location and availability of the written hazard communication program required under paragraph (a) of this section, including the list of substances identified in subpart E of this part as subject to this section, and MSDSs required by paragraph (c) of this section.

(2) Training provided to employees shall include:

(i) Methods and observations that may be used to detect the presence or release of the substance in or from an employee's work area (such as monitoring conducted by the employer, continuous monitoring devices, visual appearance, or odor of the substance when being released).

(ii) The potential human health and environmental hazards of the substance as specified in subpart E of this part.

(iii) The measures employees can take to protect themselves and the environment from the substance, including specific procedures the employer has implemented to protect employees and the environment from exposure to the substance, including appropriate work practices, emergency procedures, personal protective equipment, engineering controls, and other measures to control worker exposure and/or environmental release required under subpart E of the part, or alternative control measures which EPA has determined under § 721.30 provide substantially the same degree of protection as the specified control measures.

(iv) The requirements of the hazard communication program developed by the employer under this section, including an explanation of the labeling system and the MSDS required by this section and guidance on obtaining and using appropriate hazard information.

(e) Low concentrations in mixtures. If a substance identified in subpart E of this part is present in the work area only as a mixture, an employer is exempt from the provisions of this section if the concentration of the substance in the mixture does not exceed a concentration set in subpart E of this part. The exemption does not apply if the employer has reason to believe that during intended use or processing in the work area, the substance in the mixture may be concentrated above the level set in subpart E of this part.

(f) Existing hazard communication program. The employer need not take additional actions if existing programs and procedures satisfy the requirements of this section.

(g) Human health, environmental hazard, exposure, and precautionary statements. Whenever referenced in subpart E of this part for a substance, the following human health and environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph (b) of this section and the MSDS as specified in paragraph (c) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(1) Human health hazard statements: This substance may cause:

(i) Skin irritation.

(ii) Respiratory complications.

(iii) Central nervous system effects.

(iv) Internal organ effects.

(v) Birth defects.

(vi) Reproductive effects.

(vii) Cancer.

(viii) Immune system effects.

(ix) Developmental effects.

(2) Human health hazard precautionary statements: When using this substance:

(i) Avoid skin contact.

(ii) Avoid breathing substance.

(iii) Avoid ingestion.

(iv) Use respiratory protection.

(v) Use skin protection.

(3) Environmental hazard statements: This substance may be:

(i) Toxic to fish.

(ii) Toxic to aquatic organisms.

(4) Environmental hazard precautionary statements: Notice to users:

(i) Disposal restrictions apply.

(ii) Spill clean-up restrictions apply.

(iii) Do not release to water.

(5) Each human health or environmental hazard precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, "See MSDS for details."

(h) Human health, environmental hazard exposure and precautionary statements.

(1) Whenever referenced in subpart E of this part for a substance, the following human health, environmental hazard, exposure, and precautionary statements shall appear on each label as specified in paragraph (b) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(i) Precautionary statements.

(A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, or smoke from spray application.

(D) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals.

(ii) Human health hazard statements. This substance may cause:

(A) Skin irritation

(B) Respiratory complications

(C) Central nervous system effects

(D) Internal organ effects

(E) Birth defects

(F) Reproductive effects

(G) Cancer

(H) Immune system effects

(I) Developmental effects

(iii) Human health hazard precautionary statements. When using this substance:

(A) Avoid skin contact

(B) Avoid breathing substance

(C) Avoid ingestion

(D) Use respiratory protection

(E) Use skin protection

(iv) Environmental hazard statements. This substance may be:

(A) Toxic to fish

(B) Toxic to aquatic organisms

(v) Environmental hazard precautionary statements. Notice to Users:

(A) Disposal restrictions apply

(B) Spill clean-up restrictions apply

(C) Do not release to water.

(vi) Additional statements. Each human health or environmental precautionary statement identified in subpart E of this part for the label on the substance container must be followed by the statement, "See MSDS for details."

(2) Whenever referenced in subpart E of this part for a substance, the following human health, environmental hazard, exposure, and precautionary statements shall appear on each MSDS as specified in paragraph (c) of this section. Additional statements may be included as long as they are true and do not alter the meaning of the required statements.

(i) Precautionary statements.

(A) The health effects of this chemical substance have not been determined.

(B) When using this substance, use skin protection.

(C) Use respiratory protection when there is a reasonable likelihood of exposure in the work area from dust, mist, or smoke from spray application.

(D) Chemicals similar in structure to this substance have been found to cause cancer in laboratory animals.

(ii) Human health hazard statements. This substance may cause:

(A) Skin irritation

(B) Respiratory complications

(C) Central nervous system effects

(D) Internal organ effects

(E) Birth defects

(F) Reproductive effects

(G) Cancer

(H) Immune system effects

(I) Developmental effects

(iii) Human health hazard precautionary statements. When using this substance:

(A) Avoid skin contact

(B) Avoid breathing substance

(C) Avoid ingestion

(D) Use respiratory protection

(E) Use skin protection

(iv) Environmental hazard statements. This substance may be:

(A) Toxic to fish

(B) Toxic to aquatic organisms

(v) Environmental hazard precautionary statements. Notice to Users:

(A) Disposal restrictions apply

(B) Spill clean-up restrictions apply

(C) Do not release to water.

Credits

[55 FR 45996, Oct. 31, 1990]

AUTHORITY: 15 U.S.C. 2604, 2607, and 2625(c).

Current through July 20, 2018; 83 FR 34497

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