[NOT YET SCHEDULED FOR ORAL ARGUMENT]

No. 17-1201

IN THE UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND SCOTT PRUITT, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent,

AMERICAN CHEMISTRY COUNCIL, ET AL.,

Intervenors for Respondent.

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

FINAL BRIEF OF RESPONDENTS EPA AND SCOTT PRUITT

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), the undersigned counsel certifies as follows:

A. Parties and Amici.

All parties and intervenors are identified in Petitioner's brief.

B. Rulings Under Review.

Petitioner seeks review of the final rule of the U.S. Environmental Protection Agency entitled "TSCA Inventory Notification (Active-Inactive) Requirements," which is published at 82 Fed. Reg. 37,520 (Aug. 11, 2017).

C. Related Cases.

There are no related cases as defined by D.C. Circuit Rule 28(a)(1)(C).

s/ Phillip R. Dupré
PHILLIP R. DUPRÉ

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GLOSSARY

APA – Administrative Procedures Act

EDF – Environmental Defense Fund

EPA – Environmental Protection Agency

FOIA – Freedom of Information Act

TSCA – Toxic Substances Control Act

STATEMENT OF JURISDICTION

Petitioner Environmental Defense Fund ("EDF") challenges the final rule from the United States Environmental Protection Agency ("EPA"), "TSCA Inventory Notification (Active-Inactive) Requirements," 82 Fed. Reg. 37,520 (Aug. 11, 2017), hereinafter the "Inventory Rule." As discussed *infra* at 33-35 and 40-41, EDF lacks standing to pursue certain of its claims. This Court has jurisdiction to review EDF's remaining challenges pursuant to the Toxic Substances Control Act ("TSCA") § 19(a)(1)(A), 15 U.S.C. § 2618(a)(1)(A).

PERTINENT STATUTES AND REGULATIONS

Except for 15 U.S.C. § 2604 (reproduced in the addendum to this brief), all applicable statutes are contained in Petitioner EDF's Principal Brief.

STATEMENT OF THE ISSUES

1. Whether EPA reasonably allowed any manufacturer or processor to seek to maintain as confidential the specific chemical identity of substances it manufactures or processes where the identity of those substances is currently claimed as confidential on EPA's TSCA chemical substance inventory.

2. With respect to EDF's challenge to the questions EPA set forth in the Inventory Rule for substantiating confidentiality claims: (a) has EDF alleged a sufficiently concrete and non-speculative injury to support its claim of standing; and (b) assuming EDF has standing, has it shown that EPA's selection of substantiation questions was arbitrary, capricious, or otherwise contrary to law.

3. Whether EDF has demonstrated that it will be imminently injured by EPA's purported failure to expressly incorporate the requirements of TSCA § 14, 15 U.S.C. § 2613, into the Inventory Rule such that it has standing to challenge this aspect of the Rule, and if so, whether EPA's rule is inconsistent with TSCA § 14, 15 U.S.C. § 2613, simply because EPA did not expressly incorporate all of its requirements.

4. Whether it was reasonable for EPA not to address the assignment of unique identifiers for confidential chemical substances as part of the Inventory Rule, where TSCA states that unique identifiers are to be assigned upon approval of confidentiality claims, and that EPA need only promulgate its plan to review the confidentiality claims for these substances within 1 year *after* EPA compiles its initial revised TSCA Inventory, which is the subject of this rulemaking.

5. Whether EPA reasonably exempted export-only manufacturing from reporting under the Inventory Rule because such manufacturing is exempt from premanufacture notice requirements.

INTRODUCTION

EPA currently maintains the TSCA Inventory, which contains all existing chemical substances manufactured (including imported) or processed in the United States that do not qualify for an exemption or exclusion. In its Petition, EDF makes several challenges to EPA's Inventory Rule. The Rule imposes reporting requirements that EPA will use to update the TSCA Inventory by designating

chemical substances on the Inventory as "active" (*i.e.*, manufactured or processed for a nonexempt commercial purpose within ten years before the June 2016 amendments to TSCA, or thereafter) or "inactive" in U.S. commerce. Under the Inventory Rule, manufacturers are required, and processors are permitted, to submit a Notice of Activity to EPA letting EPA know whether they have manufactured or processed a particular chemical during the 10-year period preceding the June 2016 amendments to TSCA. When doing so, manufacturers and processors of chemical substances on the confidential portion of the Inventory may seek to maintain an existing confidentiality claim that the specific chemical identity of a substance they have manufactured or processed during that period should remain on the confidential portion of the TSCA Inventory. Whether EPA approves any particular confidentiality claim will be determined by EPA at a later juncture, separate from the EPA Inventory Rule.

EDF primarily objects to EPA's decision to allow any manufacturer or processor to seek to maintain as confidential the specific chemical identity of substances it manufactures or processes where the identity of those substances is currently claimed as confidential on the TSCA Inventory. As explained below, EPA's approach was required by the statute itself and, in any event, was a reasonable decision by EPA. EDF raises several other secondary objections; however, these too are without merit. As set forth more fully below, the Petition should be denied.

STATEMENT OF THE CASE

A. Statutory Background

1. The Toxic Substances Control Act

Congress enacted TSCA to prevent unreasonable risks to health or the environment associated with the manufacture, processing, distribution in commerce, use and disposal of certain chemical substances and mixtures. *See* 15 U.S.C. §§ 2601-97. TSCA was designed to emphasize review and potential regulation of such chemicals prior to their manufacture, processing, distribution in commerce, and use and disposal, rather than after exposure to them has already occurred. S. Rep. No. 94-698, at 5 (1976), reprinted in Legislative History of TSCA at 161; H.R. Rep. No. 94-1341, at 1, 6 (1976), reprinted in Legislative History of TSCA at 409, 414 (Comm. Print 1976). In particular, TSCA provides EPA authority to require reporting, record-keeping and testing, and to impose restrictions relating to chemical substances and/or mixtures.

Section 8(b) of TSCA, 15 U.S.C. § 2607(b), requires EPA to compile, keep current, and publish an inventory of chemical substances manufactured or processed in the United States. This shall include chemical substances reported under an original Inventory compilation and each chemical substance for which a Premanufacture Notice (commonly referred to as a "PMN") has been submitted and manufacture has commenced, as of the date such substance is manufactured in the United States. 15 U.S.C. § 2607(b)(1). However, where a chemical substance's

"identity is confidential, it is listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity." 40 C.F.R. § 720.25(b)(1); *see also* 15 U.S.C. § 2607(b)(7)(B). Thus the TSCA Inventory has two distinct sections: (1) the public portion of the Inventory, which includes all substances but uses generic chemical names and other identifiers to identify the confidential subset of substances, and (2) the confidential portion of the Inventory, which includes only the confidential subset of chemical substances, and which identifies the substances by their specific chemical identities.

Section 5 of TSCA, 15 U.S.C. § 2604, requires that any person who intends to manufacture a "new chemical substance" submit to EPA a notice of such intent at least 90 days before initiating the activity. 15 U.S.C. § 2604(a)(1). ("[N]ew chemical substance" means any chemical not on the TSCA Inventory. 15 U.S.C. § 2602(11).) In most cases, the notice required by this section is a Premanufacture Notice under 40 C.F.R. part 720. The statute exempts persons from the requirement to file a Premanufacture Notice under certain circumstances, including where the chemical substance is manufactured solely for export from the United States and certain specified requirements are met. *See* 15 U.S.C. § 2611(a)(1)(A); *see also id.* at § 2604(h).

If someone who files a Premanufacture Notice begins manufacturing the chemical substance that is the subject of the Premanufacture Notice, the person must file a Notice of Commencement pursuant to 40 C.F.R. § 720.102, upon receipt of which EPA adds the chemical substance to the TSCA Inventory. Once a chemical

substance is listed on the Inventory, in the absence of any restriction imposed by EPA, other persons may manufacture or process it without first submitting a Premanufacture Notice or other notice required under TSCA § 5, 15 U.S.C. § 2604.

An entity submitting information to EPA under TSCA may claim that the specific chemical identity of a chemical substance that is the subject of the information is confidential business information (commonly referred to as "CBI"), and should be protected from disclosure. Confidentiality claims are in general governed by TSCA § 14, 15 U.S.C. § 2613, and EPA's regulations at 40 C.F.R. part 2, subpart B. A confidentiality claim for specific chemical identity is intended to protect from disclosure the existence of the chemical substance and/or the fact that the chemical substance is (or is intended to be) manufactured by any person for commercial purposes in the United States. *See generally* 83 Fed. Reg. 5623, 5624 (Feb. 8, 2018). In order for EPA to place a specific chemical identity on the confidential portion of the Inventory, an entity submitting a Premanufacture Notice must claim that the specific chemical identity is confidential business information on both its Premanufacture Notice and its Notice of Commencement. 40 C.F.R. § 720.85.

An entity that intends to manufacture a chemical substance that is already listed on the confidential portion of the Inventory ordinarily has no obligation to submit any information to EPA prior to commencing manufacture. If an entity is unsure whether the specific substance it intends to manufacture is already on the confidential portion of the Inventory, that entity may submit an inquiry to EPA (commonly

referred to as a "bona fide"), which must establish a bona fide intent to manufacture the chemical substance, and must list the specific chemical identity of that substance. 40 C.F.R. § 720.25(b)(1)-(2). If the entity shows a bona fide intent to manufacture the chemical substance, EPA will then determine if the chemical substance identified by the entity is on the confidential portion of the Inventory. 40 C.F.R. § 720.25(b)(5). If so, EPA will notify the entity, who then may manufacture or import the substance without submitting a Premanufacture Notice. 40 C.F.R. § 720.25(b)(6).

2. Relevant Impacts of the Lautenberg Chemical Safety Act

In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"), which amended TSCA. Pub. L. No. 114-182 (June 22, 2016). The Lautenberg Act changed TSCA in a number of substantive ways, two of which are particularly relevant here.

First, the Lautenberg Act requires EPA to designate chemical substances on the TSCA Inventory as either "active" or "inactive" in U.S. commerce. 15 U.S.C. § 2607(b)(4)(A)(ii) & (iii); *see also* 82 Fed. Reg. at 37,520. This was designed to ensure that the Inventory reflects which chemical substances are *actively* manufactured and/or processed in the United States. (Previously, once a substance was placed on the Inventory, created in the 1970s, the public would not know whether the substances may have stopped being manufactured and processed in the United States, *i.e. become inactive*.) To accomplish this, the Lautenberg Act directs EPA to promulgate a rule that requires manufacturers, and may require processors, to report each chemical

substance that they manufactured or processed (as applicable) "for a nonexempt commercial purpose during the 10-year period ending on the day before June 22, 2016." 15 U.S.C. § 2607(b)(4)(A)(i); *see also* 82 Fed. Reg. at 37,521. The Lautenberg Act also requires that EPA keep those designations current via forward-looking reporting. 15 U.S.C. § 2607(b)(5).

Congress gave EPA explicit instructions addressing confidential chemical substances when compiling the active Inventory. EPA was required to:

> (i) maintain the list under paragraph (1), [the TSCA Inventory] which shall include a confidential portion and a nonconfidential portion consistent with this section and section 2613 of this title;
>
> (ii) require any manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential pursuant to section 2613 of this title to submit a notice under subparagraph (A) that includes such request;
>
> (iii) require the substantiation of those claims pursuant to section 2613 of this title and in accordance with the review plan described in subparagraph (C); and
>
> (iv) move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential from the confidential portion of the list published under paragraph (1) to the nonconfidential portion of that list.

15 U.S.C. § 2607(b)(4)(B). EPA's rule implementing this provision is being challenged here.

Congress further instructed EPA to develop a plan to review all such confidentiality claims for specific chemical identities that a person seeks to maintain pursuant to the provisions set forth above. *See* 15 U.S.C. § 2607(b)(4)(C) and (D). The review plan is to be established in a separate rule promulgated by EPA within one year of compiling the initial list of active substances on the Inventory. *Id.* at § 2607(b)(4)(C). EPA is currently compiling the initial list containing active and inactive designations, which is effectuated by the Inventory Rule. Accordingly, the Agency has not yet proposed the separate rule for establishing a plan to review confidentiality claims for specific chemical identities.

Second, the Lautenberg Act also revised the general TSCA confidential business information provisions in TSCA § 14, 15 U.S.C. § 2613, in several ways relevant to this petition. It added a procedural requirement for any person asserting a confidentiality claim for information submitted to EPA under TSCA.

> An assertion of a claim [of confidentiality] under subparagraph (A) shall include a statement that the person has—
>
> > (i) taken reasonable measures to protect the confidentiality of the information;
> >
> > (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
> >
> > (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and
> >
> > (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

15 U.S.C. § 2613(c)(1)(B). An authorized official of the claimant company must certify that this statement is true and correct. *Id.* § 2613(c)(5).

The four-part statement generally reflects the substantive requirements for protection from disclosure that are codified elsewhere under TSCA, as well as in EPA's existing regulations at 40 C.F.R. §§ 2.208 and 2.306(g). Specifically, the substantive requirements for protections from disclosure are set forth in TSCA § 14(a), 15 U.S.C. § 2613(a), which states that EPA is to apply the substantive requirements of 5 U.S.C. § 552(b)(4), the trade secrets and confidential business information provision of the Freedom of Information Act ("FOIA").

In addition, under the amended TSCA § 14(c)(3), 15 U.S.C. § 2613(c)(3), "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section." An authorized official must certify that any information submitted to substantiate the claim is true and correct. 15 U.S.C. § 2613(c)(5). The Lautenberg Act also requires EPA to review a certain subset of asserted confidentiality claims (including all claims regarding specific chemical identity where the chemical substance has been offered for commercial distribution) and to approve, approve in part and deny in part, or deny those claims within 90 days of their receipt. *See* 15 U.S.C. § 2613(g)(1).

In addition, the Lautenberg Act requires EPA to "develop a system to assign a unique identifier to each specific chemical identity for which the Administrator

approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term." 15 U.S.C. § 2613(g)(4)(A)(i).

B. Factual Background

EPA promulgated the Inventory Rule under the revised TSCA § 8(b), 15 U.S.C. § 2607(b). *See* 82 Fed. Reg. at 37,522. The Inventory Rule requires "electronic reporting of chemical identity from persons who manufactured a chemical substance for nonexempt commercial purpose during the 10-year time period ending on June 21, 2016." 82 Fed Reg. at 37,521.

EPA developed two Notice of Activity forms (commonly referred to as "NOAs") for reporting chemicals under the Inventory Rule. 82 Fed. Reg. at 37,522-23. Notice of Activity Form A "will be used for retrospective reporting," and Notice of Activity Form B "will be used for forward-looking reporting." *Id.* at 37,523. With respect to confidentiality claims, EPA's Inventory Rule provided that "[a] person submitting information under this part may request to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance, but may do so only if the identity of the chemical substance is listed on the confidential portion of the Inventory as of the time the notice is submitted for that chemical substance under this part." 40 C.F.R. § 710.37(a). "If no person submitting the information specified in [Sec.] 710.29(d)(4) for a particular chemical substance requests that the claim be maintained, EPA will treat the specific chemical identity of

that chemical substance as not subject to a confidentiality claim and will move the chemical substance to the public portion of the Inventory." *Id.*

EPA specifically defined an "existing claim for protection against disclosure of the specific chemical identity," 15 U.S.C. § 2607(b)(4)(B)(ii), as "a claim for protection of the specific chemical identity of a chemical substance that is listed on the confidential portion of the Inventory, asserted prior to June 22, 2016," 82 Fed. Reg. at 37,541 (codified at 40 C.F.R. § 710.23 (2018)).

The Inventory Rule also sets forth substantiation questions for persons to answer in support of their request to maintain a chemical identity confidentiality claim. 40 C.F.R. § 710.37(c). For retrospective reporting, persons have the option to answer these substantiation questions to avoid being subject to further substantiation requirements at a later date as will be provided in the review plan rule. *Id.* at (a)(1). Alternatively, persons may substantiate their claims in accordance with the provisions of the future review plan rule, or may rely upon substantiation previously submitted to EPA during the 5-year period before the date on which substantiation is due. For prospective reporting, persons seeking to maintain a claim of confidentiality must answer these substantiation questions, either at the time of filing their Notice of Activity Form B or within 30 days thereafter.

Claims to maintain the confidentiality of a specific chemical identity asserted by entities when submitting a Notice of Activity Form A under this Rule will be reviewed

in accordance with EPA's forthcoming review-plan rule fulfilling its obligation under 15 U.S.C. § 2607(b)(4)(C)-(D).

EPA is also separately developing a process to implement the unique identifier requirement under TSCA § 14(g)(4), 15 U.S.C. § 2613(g)(4). *See* "Assignment and Application of the 'Unique Identifier" Under TSCA Section 14; Notice of Additional Information and Opportunity to Comment," 83 Fed. Reg. 5623 (Feb. 8, 2018). EPA did not address the unique identifier requirements in this Rule.

On September 1, 2017, EDF filed a petition for review with this Court. Dkt. No. 1691492.

SUMMARY OF ARGUMENT

EDF raises several objections to EPA's Inventory Rule. EDF primarily challenges EPA's decision to allow any manufacturer or processor to seek to maintain as confidential the specific chemical identity of substances it manufactures or processes where the identity of those substances is currently claimed as confidential on the TSCA Inventory. EPA's decision was required by the statute, which mandates EPA to "require *any* manufacturer or processor of a chemical substance on the confidential portion of the [TSCA Inventory] that seeks to maintain *an* existing claim for protection against disclosure of the specific chemical identity" to submit such request when submitting their notice of activity. 15 U.S.C. § 2607(b)(4)(B) (emphasis added). Even if the statute were ambiguous on this point, EPA's interpretation is reasonable and entitled to deference.

Second, EDF objects to the substantiation questions entities submitting certain Notice of Activity forms must answer to maintain a confidentiality claim for a specific chemical identity. EDF does not have standing to challenge EPA's substantiation questions because it has not shown that the removal of one substantiation question will make any difference in EPA's ultimate merits determination on a confidentiality claim. Moreover, EPA's decision regarding substantiation questions was well within the discretion Congress gave it to formulate them.

Third, EDF argues that the Inventory Rule ignores, and will result in EPA's noncompliance with, procedural requirements set forth in TSCA § 14, 15 U.S.C. § 2613, relating to EPA's review of confidentiality claims. EDF has shown no risk of imminent injury and lacks standing to challenge these aspects of the Inventory Rule. Moreover, EDF merely speculates that EPA's compliance with the Inventory Rule will somehow lead to noncompliance with TSCA § 14, 15 U.S.C. § 2613. Instead, EPA must follow, and fully intends to follow, all statutory requirements regarding confidentiality claims when implementing the Inventory Rule.

Fourth, EDF argues that EPA failed to address the assignment of unique identifiers to confidential chemical substances during this rulemaking. But, Congress directed EPA to assign unique identifies only *after* approving the confidentiality claims, which need not occur until after EPA's promulgation of the review plan rule.

Fifth, EPA reasonably exempted export-only manufacturing from reporting under the Inventory Rule because such manufacturing is exempt from

premanufacture notice requirements. While TSCA § 12, 15 U.S.C. § 2611, does not mandate the exemption of export-only manufacturing from the general statutory requirements of TSCA § 8, 15 U.S.C. § 2607, under which EPA promulgated the Inventory Rule, it also does not prohibit EPA from exempting export-only manufacturers from its requirements set forth under TSCA § 8(b)(4)-(5), 15 U.S.C. § 2607(b)(4)-(5), when such exemption is consistent with the requirements and purpose of that subsection.

STANDARD OF REVIEW

The final rule is subject to judicial review as set forth in TSCA § 19, 15 U.S.C. § 2618. For rules promulgated under TSCA § 8, 15 U.S.C. § 2607, such as the Inventory Rule, "[u]pon the filing of a petition . . . for judicial review of a rule or order, the court shall have jurisdiction (i) to grant appropriate relief, including interim relief, as provided in chapter 7 of title 5 [of the Administrative Procedure Act ("APA")], and (ii) . . . to review such rule or order in accordance with chapter 7 of title 5 [of the APA]." 15 U.S.C. § 2618(c)(1)(A). Under the APA, the court may set aside final EPA action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The "arbitrary or capricious" standard presumes the validity of agency action, and a reviewing court is to uphold the action if it satisfies minimum standards of rationality. *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 519 (D.C. Cir. 2009).

The court must affirm as long as EPA considered all relevant factors and articulated a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962); *see also Milk Indus. Found. v. Glickman*, 132 F.3d 1467, 1476 (D.C. Cir. 1998). While agency actions are subject to careful scrutiny, they are presumed to be valid and are upheld if they "conform to certain minimal standards of rationality." *Small Refiner Lead Phase-Down Task Force v. EPA*, 705 F.2d 506, 520-21 (D.C. Cir. 1983) (internal quotation marks and citation omitted).

Challenges to EPA's statutory interpretations are governed by *Chevron, U.S.A., Inc. v. NRDC, Inc.*, 467 U.S. 837, 842-44 (1984). The court first inquires whether Congress "has directly spoken to the precise question at issue," in which case the court "give[s] effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. If the statute is "silent or ambiguous," however, the court considers "whether the agency's answer is based on a permissible construction." *Id.* at 843. Where the legislative delegation of interpretive authority to an agency "is implicit . . . a court may not substitute its own construction . . . for a reasonable interpretation made by the administrator of an agency." *Id.* at 844.

With respect to establishing Article III standing, "[t]he party invoking federal jurisdiction bears the burden of establishing" standing. *Clapper v. Amnesty Int'l USA*, 568 U.S. 398, 411–12 (2013) (citation omitted). "Since they are not mere pleading requirements but rather an indispensable part of the plaintiff's case, each element

must be supported in the same way as any other matter on which the plaintiff bears the burden of proof, *i.e.*, with the manner and degree of evidence required at the successive stages of the litigation." *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561 (1992).

ARGUMENT

I. EPA Reasonably Allowed Any Manufacturer or Processor To Seek to Maintain as Confidential the Specific Chemical Identity of Substances It Manufactures or Processes Where the Identity of Those Substances Are Currently Claimed as Confidential.

In developing the Inventory Rule, EPA was directed to "require any manufacturer or processor of a chemical substance on the confidential portion of the list . . . that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential . . . to submit a notice under subparagraph (A) that includes such request." 15 U.S.C. § 2607(b)(4)(B)(ii). EPA concluded that this allows *any* manufacturer or processor of a chemical substance on the confidential portion of the list submitting a Notice of Activity Form A or B to seek to maintain an existing confidentiality claim that caused EPA to place the substance on the confidential portion of the Inventory. First, EPA's reading of the statutory requirements is required by the plain language of the statute. Second, to the extent the statutory language is ambiguous on this point, EPA's interpretation is entitled to deference under *Chevron*, 467 U.S. 837.

A. The Statute's Plain Language Confirms That Any Manufacturer or Processor Should Be Allowed to Maintain an Existing Confidentiality Claim for Specific Chemical Identity.

The text of the Lautenberg Act confirms EPA's decision to allow any manufacturer or processor submitting a Notice of Activity Form A or B to seek to maintain a confidentiality claim for the protection of a specific chemical identity, where that specific chemical identity is currently listed on the confidential portion of the Inventory. Congress directed that:

> the Administrator shall . . . (ii) require *any* manufacturer or processor of a chemical substance on the confidential portion of the list published under paragraph (1) that seeks to maintain *an* existing claim for protection against disclosure of the specific chemical identity of the chemical substance as confidential pursuant to section 2613 of this title to submit a notice under subparagraph (A) that includes such request . . .

15 U.S.C. § 2607(b)(4)(B) (emphasis added); *see also id.* § 2607(b)(5)(B).

Here, Congress stated that "*any* manufacturer or processor of a chemical substance on the confidential portion of the [Inventory]" could seek to maintain a confidentiality claim. *Id.* at 2607(b)(4)(B)(ii) (emphasis added). "'[R]ead naturally, the word 'any' has an expansive meaning, that is, one or some indiscriminately of whatever kind.'" *New York v. EPA*, 443 F.3d 880, 885 (D.C. Cir. 2006) (quoting *United States v. Gonzales*, 520 U.S. 1, 5 (1997)). EDF wishes to narrow Congress's statement here to limit the category of manufacturers or processors who may seek to maintain a claim to only those who did so previously. Environmental Defense Fund's Principal Brief ("EDF Br.") at 30-43. However, "[t]he word 'any' . . . undercuts the attempt to

impose this narrowing construction." *Salinas v. United States*, 522 U.S. 52, 57 (1997). EDF points to no persuasive reason to show that "the usual tools of statutory construction should not apply and hence no reason why 'any' should not mean 'any.'" *New York*, 443 F.3d at 886.

Further, Congress stated that any manufacturer or processor of a chemical substance on the confidential portion of the Inventory could "seek[] to maintain *an* existing claim." 15 U.S.C. § 2607(b)(4)(B)(ii) (emphasis added). Congress chose to use the indefinite article "an," rather than use a possessive determiner, such as "their" or "its." Indeed, EDF's argument, if accepted, would essentially re-write this statute to refer to a "manufacturer or processor . . . that seeks to maintain *[its]* existing claim for protection against disclosure of the specific chemical identity." *Id.* However, this is not the language Congress chose. Rather, EPA appropriately "give[s] effect to each word of a statute," *New York*, 443 F.3d at 885, and, as a result, does not require the manufacturer or processor to only be able to maintain a claim it originally submitted.

EDF erroneously argues that "[a] person can only maintain an existing claim if the person (or their predecessor-in-interest) previously made the claim." EDF Br. at 31. However, disclosure of the fact that a specific chemical substance is being used in U.S. commerce can cause competitive harm to multiple companies, even if only one of them previously submitted information to EPA asserting the confidentiality claim. EDF does not dispute that more than one entity may have a valid claim of confidentiality for a specific chemical identity. *See* EDF Br. at 38. Indeed, existing

EPA regulations expressly provide for this possibility. *See* 40 C.F.R. §§ 2.204(c), 2.205(d)(3).

A confidentiality claim for chemical identity may be made by, *inter alia*, someone who submits information to EPA containing the chemical identity, and wishes to protect against "*public* disclosure of the fact that anyone manufactures or imports the new chemical substance for commercial purposes." 40 C.F.R. § 720.85(b)(2)(i) (Premanufacture Notice regulations) (emphasis added). More than one company may manufacture the same chemical substance, and so long as each company treats the chemical identity as confidential and the chemical identity has not been disclosed, the public, including other potential competitors, will be unaware of the fact that anyone manufactures or imports the new chemical substance for commercial purposes.

The actions of any one company to publicly disclose the specific chemical identity of a chemical substance might defeat a confidentiality claim for that chemical identity to the detriment of anyone else claiming or treating that chemical identity as confidential business information. But so long as the chemical identity has not been made public or become generally known in an industry, another company may legitimately benefit from that confidentiality, even if that company had not submitted the chemical identity information to EPA and thus had no occasion to assert a separate confidentiality claim for the identity of that chemical substance.

And in fact, EPA's longstanding confidentiality regulations have sought to protect the interests of a business which, "although it has not asserted a claim, might be expected to assert a claim if it knew EPA proposed to disclose the information." 40 C.F.R. § 2.204(c)(2)(i); *see also id.* § 2.201(d) (defining "Affected business" to include such a business). These regulations provide that when determining whether business information in the Agency's possession is entitled to confidential treatment (such as in response to a FOIA request), if EPA's examination discloses the existence of a business which "might be expected to assert a claim if it knew EPA proposed to disclose the information," but which has neither asserted a claim nor waived, withdrawn, or otherwise failed to assert a claim when submitting information to EPA, then the relevant EPA office "shall contact a responsible official of each such business to learn whether the business asserts a claim covering the information." 40 C.F.R. § 2.204(c)(2)(i).

EPA's approach under the Inventory Rule, which allows for any manufacturer or processor of a chemical substance on the confidential portion of the Inventory to seek to maintain an existing claim, defined an existing claim based on date of assertion and on whether the chemical substance is currently "listed on the confidential portion of the Inventory," 82 Fed. Reg. at 37,541. This comports with the statute's text and structure and EPA's long-standing practice in processing confidentiality claims. *See* 15 U.S.C. § 2607(b)(4)(B)(ii), (b)(5)(B)(ii), (b)(8). Nowhere under TSCA § 8, 15 U.S.C. § 2607, does Congress indicate that it intended to narrowly limit the "existing claims"

that may be maintained to those that had been asserted by the same person who is now reporting under the Inventory Rule.

Indeed, EDF's interpretation would render much of TSCA section 8(b)(8), 15 U.S.C. § 2607(b)(8), superfluous.

> No person may assert a new claim under [TSCA section 8(b)] or section 14 for protection from disclosure of a specific chemical identity of any active or inactive substance for which a notice is received under paragraph (4)(A)(i) or (5)(B)(i) [i.e., the Notice of Activity Form A or B] *that is not on the confidential portion of the [Inventory]*.

15 U.S.C. § 2607(b)(8) (emphasis added). Here, Congress plainly barred only new confidentiality claims with respect to any active or inactive substance "that is not on the confidential portion of the [Inventory]." *Id.* Congress did not bar all new confidentiality claims through the Notice of Activity Forms A or B. Indeed, EDF's interpretation of § 2607(b)(4)(B) renders the barring of new claims for chemicals "*that are not on the confidential portion of the [Inventory*]" superfluous as applied to claims under TSCA § 8(b), 15 U.S.C. § 2607(b). If Congress had intended to flatly bar new claims under this subsection, it would have said so.[1]

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[1] Congress treated a request to maintain an existing claim under TSCA §§ 8(b)(4)(B) and 8(b)(5)(B), 15 U.S.C. §§ 2607(b)(4)(B) and 2607(b)(5)(B), as the assertion of a claim. For example, § 8(b)(4)(C), 15 U.S.C. § 2607(b)(4)(C), describes requests to maintain existing claims for specific chemical identity as "claims to protect the specific chemical identities of chemical substances on the confidential portion of the [Inventory] that are *asserted* pursuant to" the Notice of Activity process (emphasis added). *See also id.* § 2607(b)(4)(D)(i) (referring to "all manufacturers and processors *asserting* claims under subparagraph (B)") (emphasis added). Whether or not such a claim is viewed as "new" is a semantic matter with no legal significance. Congress

EDF cites several provisions of TSCA § 14, 15 U.S.C. § 2613, that it asserts show that Congress did not intend for a manufacturer or processor who had not previously asserted a confidentiality claim to be able to maintain an existing confidentiality claim. In particular, EDF points to provisions of TSCA addressing withdrawal of claims, who is entitled to notice upon the expiration of claims, and who is entitled to notice and appeal upon denial of claims. EDF Br. at 33-34. While these provisions, added or amended by the Lautenberg Act, show how Congress intended for certain aspects of confidentiality claim management to be handled in future stages of the regulatory process, 15 U.S.C. § 2613, they do not reveal Congress' intent with respect to the process by which any manufacturer or processor of a chemical substance on the confidential portion of the Inventory may seek to maintain pre-Lautenberg Act claims under the specific procedure established by TSCA §§ 8(b)(4)-(5), 15 U.S.C. §§ 2607(b)(4)-(5).

Fundamentally, EDF appears to be conflating EPA's decision regarding who may *seek to maintain* a confidentiality claim with EPA's separate, substantive requirements for *approving* a confidentiality claim. Indeed, were an entity to "claim confidentiality for its information merely on the basis that another person treats the

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either viewed such claims as permissible new claims, or did not view them as "new" within the meaning of TSCA § 8(b), 15 U.S.C. § 2607(b). The point is that Congress plainly allowed for the assertion of claims through the Notice of Activity process to protect the confidentiality of the specific chemical identify of chemical substances that are already on the confidential portion of the Inventory.

information as confidential," as suggested by EDF, EDF Br. at 36, it seems highly unlikely that the entity would be able to substantiate its claim pursuant to 40 C.F.R. § 710.37(c), or certify to the truth and accuracy of the statement required for claim submissions under 40 C.F.R. § 710.37(e). As a result—even though EPA has yet to begin its review of such confidentiality claims—a claim submitted solely on the basis that another entity treats the specific chemical identity as confidential would almost certainly not be approved.

Here, this Court need only address the narrow issue raised by the Inventory Rule, namely who may seek to maintain an existing claim of confidentiality—not whether individual claims should ultimately be approved or denied following the substantiation and review process. With respect to the narrow question presented, Congress' decision to permit "*any* manufacturer or processor of a chemical substance on the confidential portion of the [Inventory] . . . to maintain *an* existing claim," "directly sp[eaks] to the precise question at issue." *Chevron*, 467 U.S. at 842.

B. EPA's Decision to Allow Any Manufacturer or Processor to Maintain a Confidentiality Claim Was Reasonable.

To the extent that this Court determines that 15 U.S.C. § 2607(b)(4)(B)(ii) is "silent or ambiguous" as to whether any manufacturer or processor of a chemical substance on the confidential portion of the Inventory may seek to maintain an existing confidentiality claim for specific chemical identity, EPA's interpretation of the

statute is "based on a permissible construction" and is not plainly erroneous or inconsistent, and therefore should be upheld. *Chevron*, 467 U.S. at 843.

As discussed above, Congress provided that "any manufacturer or processor of a chemical substance on the confidential portion of the [Inventory]" may seek to "maintain an existing claim," and Congress considered the request to maintain a claim to be the assertion of a claim under section 8(b). *See, e.g.*, TSCA § 8(b)(4)(B), (C), (D), 15 U.S.C. § 2607(b)(4)(B), (C), (D). Moreover, Congress explicitly barred the assertion of a new claim through the Notice of Activity process to protect the confidential identity of a chemical substance "that is not on the confidential portion of" the Inventory. TSCA § 8(b)(8), 15 U.S.C. § 2607(b)(8). This proviso regarding the confidential portion of the Inventory would be superfluous as applied to claims under TSCA § 8(b), 15 U.S.C. § 2607(b), if Congress had intended to bar *any* new claims under this subsection. As discussed above, EPA believes this demonstrates that Congress intended to allow manufacturers and processors of chemicals on the confidential portion of the Inventory to assert claims for chemicals that are on the confidential portion, by seeking to maintain existing claims through the Notice of Activity process, even if those claims were initially asserted by others. But, to the extent that the statutory text is ambiguous in this regard, EPA's interpretation is clearly permissible.

As EPA explained in its proposed rule preamble, 82 Fed. Reg. 4255, 4261 (Jan. 13, 2017), final rule preamble, 82 Fed. Reg. at 37,527, and response to comments,

allowing any manufacturer or processor of a chemical substance on the confidential portion of the Inventory to seek to maintain an existing confidentiality claim is necessary to ensure that manufacturers and processors who did not previously have the opportunity to submit a confidentiality claim to EPA may seek to maintain the confidential status of a specific chemical identity in the new regulatory regime.

> A number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, even when such persons did not originally report that chemical identity to EPA and therefore were not in a position to assert a CBI claim for that chemical identity. Congress could not have intended that such companies would be forced to rely on another company to request to maintain the claim. For example, due to mergers, acquisitions, or other business events, the initial claimant may no longer exist or may no longer manufacture or process the chemical substance, or may simply fail to file the required NOA. EPA does not believe that Congress intended for specific confidential chemical identities to be disclosed without providing the opportunity for manufacturers and processors to make a request that the identities should remain confidential simply because the original claimants did not file under TSCA section 8(b)(4)(B)(ii).

JA180 (Response to Comments).

EDF concedes that "[a]llowing claims in the limited circumstances of mergers and acquisitions fits the statutory text," EDF Br. at 41, but appears to argue that there are *no other possible circumstances* under which a person would not have had a prior opportunity to assert their confidentiality claim to EPA, *see* EDF Br. at 38-41. Instead, EDF insists that "anyone who manufactured a chemical and wanted to maintain a claim of confidentiality had to assert that claim before now or risk waiving that claim." EDF Br. at 38. As explained below, EDF's factual premise is incorrect

with regard to manufacturers, and fails to account in any way for processors. EPA's decision to allow any manufacturer or processor of a chemical on the confidential portion of the Inventory to seek to maintain an existing claim considered and reasonably addressed the possibility that some manufacturers and processors may have acted in reliance upon the confidential status of a chemical identity without ever having been in a position to assert a confidentiality claim on their own behalf. Given the potential for substantial competitive harm in disclosing this information, EPA reasonably concluded that such manufacturers and processors should not be precluded from seeking to maintain the confidential status of a specific chemical identity now.

First, and for the first time in its brief, EDF erroneously asserts that "anyone who began manufacturing a confidential chemical *after* the Inventory was first compiled had to submit either a notice of bona fide intent (to determine whether it was on the Inventory), a premanufacture notice (if the chemical was not on the Inventory), or both," and thus would have had the opportunity to assert their confidentiality claim to EPA at the time of those submissions. EDF Br. at 40. Importantly, EDF never raised this argument during the rulemaking. *See* JA027 and JA094. As a result, EDF waived this argument and deprived EPA of the ability to squarely address it during the rulemaking. *See Nat'l Wildlife Fed'n v. EPA*, 286 F.3d 554, 562 (D.C. Cir. 2002) ("It is well established that issues not raised in comments

before the agency are waived and this Court will not consider them."); *see also Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1290 (D.C. Cir. 2004).

Had EDF raised this argument during the rulemaking, EPA would have provided a more detailed rebuttal of the argument in the rulemaking record. In brief, though, there are multiple scenarios under which a manufacturer would have had no need to submit either a Premanufacture Notice or a bona fide. Indeed, except in limited circumstances, there is no statutory or regulatory requirement to submit *any* notice to EPA prior to manufacturing a substance that is already listed on the Inventory. Manufacturers have the option of submitting a bona fide to EPA to verify the Inventory status of a chemical substance, but there is no legal requirement to do so. *See* 40 C.F.R. § 720.25(b)(1) (providing that a person "may" submit such inquiry to EPA). Manufacturers may assure themselves that a chemical substance is listed on the Inventory and thus authorized to be in commerce via other means—such as through third parties with whom they have contractual or other relationships. For example, an importer (which constitutes a manufacturer under TSCA) may receive assurance of a chemical substance's Inventory status from its supplier. Simply put, it is generally a violation of TSCA to manufacture a chemical substance that is not on the Inventory, but the statute and regulations impose no specific procedure to ascertain the Inventory status of a chemical being manufactured.

Moreover, even in cases where it is necessary to submit a Premanufacture Notice (or other report under TSCA), only one manufacturer in a co-manufacturer or

contract arrangement would have been required to file such notice with EPA. *See* 40 C.F.R. § 720.22(a)(2). The other manufacturer would not have been required to submit a notice to EPA, and hence may not have been in a position to assert a confidentiality claim on its own behalf—but may nevertheless have relied upon and benefitted from the confidential status of the specific chemical identity, and may have reason to seek to maintain such status under the Inventory Rule.[2] EPA's approach in the Rule ensures that manufacturers under scenarios such as those described above would have the opportunity to seek to maintain an existing confidentiality claim for specific chemical identity.

Second, EPA's interpretation is reasonable because it specifically addresses the inclusion of processors as one of the entities that *may* report chemicals to EPA. The Lautenberg Act specifically allows processors of chemicals on the confidential portion of the Inventory to maintain an existing claim of confidentiality. 15 U.S.C. § 2607(b)(4)(B)(ii). Processors, however, have limited reporting requirements under TSCA, and thus would not typically have been in a position to assert a confidentiality claim to EPA in a prior submission. For example, Premanufacture Notices are only

[2] Under the Inventory Rule, persons who co-manufacture a chemical substance "may determine among themselves who should make the required submission." 40 C.F.R. § 710.33; *see also id.* at § 710.3(d), *Manufacture* (referring to co-manufacture). Thus, the co-manufacturer who submits a Notice of Activity Form under the Inventory Rule need not be the same co-manufacturer who earlier submitted a Premanufacture Notice.

required to be submitted by persons who intend to *manufacture* a new chemical substance, *see* 15 U.S.C. § 2604(a)(1)(A)(i), 40 C.F.R. § 720.22; there is no corresponding reporting requirement for processors. Thus, processors would have had no occasion to file either a Premanufacture Notice or a bone fide. EPA's interpretation is necessary to give effect to Congress' decision to allow processors to seek to maintain a specific chemical identity on the confidential portion of the Inventory, as few processors would be able to do so under EDF's interpretation.

EDF attempts to allay concerns that its approach would force EPA to move from the confidential portion of the Inventory to the public portion of the Inventory some subset of chemicals for which manufacturers or processors currently have legitimate but previously unasserted confidentiality interests. Specifically, EDF states that "TSCA § 14 provides a separate mechanism for people to make *new* claims of confidentiality," and that EPA "arguably could have permitted manufacturers and processors to assert and concurrently substantiate new claims for confidentiality for specific chemical identities through that process." EDF Br. at 42 (emphasis in original); *see also* JA106-107 (EDF Comments). However, the Lautenberg Act is clear: if no request is received under the Inventory Rule to maintain an existing confidentiality claim for an active substance's specific chemical identity, EPA "shall" move that chemical identity from the confidential portion of the Inventory to the public portion. Once a chemical identity is moved to the public portion of the Inventory, "[n]o person may assert a new claim" to protect that specific chemical

identity from disclosure, under either TSCA § 8, 15 U.S.C. § 2607, or TSCA § 14, 15 U.S.C. § 2613. 15 U.S.C. § 2607(b)(8). Thus, the statute simply does not allow for the assertion of a "new" chemical identity confidentiality claim under TSCA § 14, 15 U.S.C. § 2613, as a substitute for seeking to maintain an existing claim under § 8, 15 U.S.C. § 2607. If a manufacturer or processor of an active chemical substance is not permitted to seek to maintain the chemical identity's confidential status under the process set forth under the Inventory Rule, that person may very well forever lose their right to seek protection from EPA's disclosure of the specific chemical identity—for example, because the company that asserted the original claim is no longer in business—even where such disclosure would cause substantial harm to the person's competitive position. It is implausible that Congress would have intended this outcome.

In sum, to the extent the Court finds there is ambiguity as to whether the statute requires that any manufacturer or processor of a chemical substance on the confidential portion of the Inventory may seek to maintain an existing confidentiality claim for specific chemical identity, EPA's interpretation of the statute is well-reasoned and should be upheld.

II. EDF Does Not Have Standing to Challenge EPA's Selection of Substantiation Questions and EPA's Selection of Substantiation Questions Was Reasonable.

Both before and after the Lautenberg Act, TSCA § 14(a), 15 U.S.C. § 2613(a), has incorporated FOIA Exemption 4's protection of trade secrets and confidential

business information, 5 U.S.C. § 552(b)(4), as the basic framework for determining whether information is eligible for protection from disclosure under TSCA. The Lautenberg Act does not change this basic substantive requirement for confidentiality determinations under TSCA, which remains consistent with the substantive criteria for confidentiality determinations set forth in EPA's regulations at 40 C.F.R. §§ 2.306(g) and 2.208. The Lautenberg Act did, however, add various procedural requirements for the assertion of confidentiality claims, including that an assertion of confidentiality be accompanied by a certified statement

> that the person has (i) taken reasonable measures to protect the confidentiality of the information; (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law; (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering."

15 U.S.C. § 2613(c)(1)(B); *see also id.* § 2613(c)(5). The TSCA amendments also separately require persons asserting confidentiality claims to "substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section." 15 U.S.C. § 2613(c)(3).

In the proposed rule, EPA set forth eleven substantiation questions to be codified in 40 C.F.R. § 710.37(a)(1)(iii). One of those was: "If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?" 82 Fed. Reg. at 4268.

This question was eliminated in the final rule. EPA explained that it has "rewritten the substantiation questions . . . to more succinctly secure answers for the basis of the CBI assertions for each data elements as well as the CBI concerns on the linkage of data elements." 82 Fed. Reg. at 37,537.

EDF claims that EPA's decision to revise the substantiation questions, and eliminate the specific question regarding reverse engineering,[3] violates the APA because it: (1) was arbitrary and capricious, EDF Br. at 44-45; and (2) violated notice-and-comment requirements by not giving EDF an opportunity to comment on the final substantiation questions, *id.* at 48. As an initial matter, EDF has failed to demonstrate that EPA's decision to not ask this substantiation question will cause it any injury; thus, EDF does not have standing to challenge this decision. But, even if this Court reviews EPA's decision, EDF is wrong on both counts.

A. EDF Does Not Have Standing to Challenge EPA's Selection of Substantiation Questions.

It is well-settled that standing "is not dispensed in gross" and that a party "must demonstrate standing for each claim he seeks to press and for each form of relief that is sought." *Town of Chester v. Laroe Estates, Inc.*, 137 S. Ct. 1645, 1650-51 (2017) (citations omitted). EDF does not have standing to challenge this aspect of the

[3] EDF vaguely asserts that "EPA eliminated the *questions* that addressed" reverse engineering, EDF Br. at 46 (emphasis added), but only identifies one particular question not selected by EPA. EPA accordingly focuses on this particular question.

Rule because EDF has not sufficiently alleged an "injury in fact" that is "actual or imminent" and "fairly . . . trace[able] to the challenged action of the defendant," nor has it shown that it is "'likely,' as opposed to merely 'speculative,' that [its] injury will be 'redressed by a favorable decision.'" *Lujan*, 504 U.S. at 560-561 (citation omitted). EDF alleges informational injury, *i.e.* that it suffers when EPA does not disclose specific chemical identities that are required to be disclosed. *See* EDF Br. at 18-19.

With respect to EDF's argument regarding the substantiation questions, EDF asserts that it "will . . . receive the information [regarding a specific chemical identity] where EPA correctly denies confidentiality claims after following all of the substantive and procedural requirements of TSCA § 14." EDF Br. at 29. However, as discussed above, EPA's decision to drop the reverse-engineering substantiation question was simply intended to make the substantiation questions more tailored, useful and efficient, and it in no way altered the separate requirement that any claimant must "certify that it is true and correct that . . . (4) I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 40 C.F.R. § 710.37(e). Thus, for EDF to suffer any injury at all from this aspect of the final rule, it would have to be presumed that a claimant would certify that the confidential information "is not readily discoverable through reverse engineering," but then would turn around and contradict that certification in some way in response to a substantiation question regarding whether the "the chemical substance [can] be identified by analysis of the product," 82 Fed. Reg. at 4268, *i.e.* reverse-engineered.

EDF has provided no basis on which to assume that such an illogical circumstance would ever arise, nor, more generally, why EPA's review of confidentiality claims would result in any different decision with or without this specific substantiation question. In short, EDF has not shown that it is "'likely,' as opposed to merely 'speculative,'" *Lujan*, 504 U.S. at 561, that inclusion of this particular question would lead EPA to disapprove—or would cause a potential claimant not to submit—a request to maintain a specific chemical identity on the confidential portion of the TSCA Inventory. Accordingly, this challenge should be dismissed for lack of standing.

B. EPA Was Not Required to Include Any Particular Substantiation Questions and Its Selection of Questions Was Reasonable.

Under TSCA § 14(c)(3), 15 U.S.C. § 2613(c)(3), a person asserting a confidentiality claim "shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section." EDF reads into the statute additional requirements regarding substantiation that are unsupported by the text. Under 15 U.S.C. § 2613(c)(1)(B), an assertion of a confidentiality claim must include a *statement* attesting to certain aspects of the claim, including that the applicant has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." Separately, an applicant is required to substantiate its confidentiality "*claim*." 15 U.S.C. § 2613(c)(3) (emphasis added). EDF misreads 15 U.S.C. § 2613(c)(3) as requiring an applicant to substantiate

the *statements* it makes in support of its claim pursuant to 15 U.S.C. § 2613(c)(1)(B). *See* EDF Br. at 46-47. But Congress never directed EPA to require applicants to substantiate *specific statement*s made in support of their claims, and thus EDF's argument that the rule violates Congress' directive on this basis must fail.

Even if review were appropriate, "when a statute uses the permissive 'may' rather than the mandatory 'shall,' 'this choice of language suggests that Congress intends to confer some discretion on the agency, and that courts should accordingly show deference .'" *Appalachian Power Co. v. EPA*, 135 F.3d 791, 807 (D.C. Cir. 1998) (quoting *Dickson v. Secretary of Defense*, 68 F.3d 1396, 1401 (D.C. Cir. 1995)). Had Congress intended for EPA to craft substantiation questions closely tied to the four required statements, it could have clearly done so. Instead, it merely authorized, but did not require, EPA to promulgate rules addressing substantiation. In this regard, it was reasonable for EPA to streamline the eleven proposed questions down to a more succinct six, and in particular to eliminate a redundant question relating to reverse engineering that would provide no more information than the statement required by both TSCA and the Inventory Rule at 40 C.F.R. § 710.37(e).

In sum, the substantiation questions included in the final rule were rewritten "in a manner intended to more succinctly secure answers for the basis of the CBI assertions for each data element as well as the CBI concerns on the linkage of data elements." JA181 (Response to Comments). That is a reasonable basis for EPA's

selection of questions, and thus EPA's decision regarding which substantiation questions to ask applicants falls well within the discretion afforded to EPA.

C. EPA's Final List of Substantiation Questions Was a Logical Outgrowth of Its Proposed List.

EDF argues that EPA's decision to change the substantiation questions from the proposed to final rule violates the APA's notice-and-comment requirements. EDF Br. at 48-49. But, "[t]hat the final rule differed from the one [] proposed is hardly unusual." *Nat'l Mining Ass'n v. Mine Safety & Health Admin.*, 512 F.3d 696, 699 (D.C. Cir. 2008). "Agencies often 'adjust or abandon their proposals in light of public comments or internal agency reconsideration.'" *Id.* (quoting *Kooritzky v. Reich*, 17 F.3d 1509, 1513 (D.C. Cir. 1994)).

EPA's proposed rule set forth a number of substantiation questions for public comment. *See* 82 Fed. Reg. at 4262 (requesting comment on all aspects of the proposed rule), 4268 (setting forth proposed substantiation questions). Multiple commenters asked EPA to reduce the scope of the confidential business information substantiation questions. JA060; JA043. EDF also asked EPA to revise certain substantiation questions. JA107. The comments are evidence of the fact that the proposal put stakeholders—including petitioners—on notice that the content and scope of the questions was at issue, and that the final questions might vary from those proposed. *See Nat. Res. Def. Council, Inc. v. Thomas*, 838 F.2d 1224, 1243 (D.C. Cir.

1988) (public comments proposing the approach the agency adopted gave other parties "a clear opportunity to shoot the idea down" during the rulemaking process).

EPA addressed the commenters' concerns, both clarifying its proposed substantiation questions to not suggest that information in Inventory notifications could be "permanently" protected from disclosure, and by reducing the number of substantiation questions. *See* JA180-181; 185-186 (Response to Comments). "[B]y comparing the final rule to the one proposed, [and] tak[ing] into account the comments, statements and proposals made during the notice-and-comment period," it is apparent that EPA's final substantiation questions constitute a "logical outgrowth" of the proposed rule, and thus should be upheld.[4] *Nat'l Mining Ass'n*, 512 F.3d at 699.

III. EDF Has Failed to Allege That It Will Be Imminently Injured by EPA's Purported Failures to Expressly Incorporate the Requirements of TSCA § 14, 15 U.S.C. § 2613, Into the Rule.

EPA's Inventory Rule states that confidentiality claims will be "treated and disclosed in accordance with 40 CFR part 2, subpart B," 40 C.F.R. 710.37(b). This of course is appropriate, as 40 C.F.R. part 2, subpart B, governs EPA's general handling of business information—under TSCA and the other environmental statutes EPA administers—which is or may be entitled to confidential treatment, and

[4] EDF also erroneously asserts that EPA failed to respond when "EDF and one industry commenter alerted EPA to the failure of the proposed rule to address the § 14 requirements clearly." EDF Br. at 49. EPA responded to these comments. *See* JA180-181 (Response to Comments) (addressing comment of the Independent Lubricant Manufacturers Association) and JA183 (addressing EDF's comment).

determinations by EPA of whether information is entitled to confidential treatment for reasons of business confidentiality, particularly in the context of requests for disclosure under FOIA. EDF does not dispute that this section applies as a general matter to confidentiality claims submitted under the Inventory Rule.

However, EDF argues that the Inventory Rule, by requiring compliance with this pre-existing regulation, "fails to incorporate the procedural requirements of TSCA § 14." EDF Br. at 49. Specifically, EDF appears to be concerned that following the assertion of confidentiality claims in notices submitted under the Inventory Rule: (1) EPA will not review certain of those claims within a 90-day window as required under TSCA § 14(g)(1), 15 U.S.C. § 2613(g)(1); (2) upon EPA's denial of a claim, EPA will not inform the claimant of their right to appeal within 30 days by bringing an action in district court to restrain disclosure, pursuant to TSCA § 14(g)(2), 15 U.S.C. § 2613(g)(2); and (3) EPA will not make nonconfidential aspects of its confidential business information determinations public pursuant to a general provision in TSCA § 26(j), 15 U.S.C. § 2625(j), regarding availability of information. *See* EDF Br. at 50-52. However, as EDF has not shown that EPA's compliance with the Inventory Rule will lead to noncompliance with any of these statutory provisions, EDF is at no imminent risk of injury and lacks standing to challenge these aspects of the Inventory Rule. *See Town of Chester*, 137 S. Ct. at 1650-51. Indeed, EPA must, and fully intends to, follow all statutory requirements regarding confidentiality claims when implementing the Inventory Rule, and never indicated otherwise in the Rule.

A. As EDF Identifies No Action That Fails to Comply With TSCA, EDF Is At No Risk of Suffering Imminent Injury.

EDF does not have standing to bring this challenge to the Inventory Rule because EDF has not sufficiently alleged an "injury in fact" that is "actual or imminent." *Lujan*, 504 U.S. at 560. Indeed, while EDF does not specifically address this argument in its standing section, it appears that EDF alleges that because EPA did not expressly incorporate the procedural requirements of TSCA § 14, 15 U.S.C. § 2613, into this Rule, EPA will simply decline to follow those statutory requirements when reviewing and deciding confidentiality claims asserted under the Rule. EDF Br. at 49-52. But such an argument has no basis in fact, as EDF has neither proven nor alleged that EPA would be unable to—or even unlikely to—comply with both the Inventory Rule and relevant provisions of TSCA.

The requirements of TSCA § 14, 15 U.S.C. § 2613, bind EPA by their own terms. EPA must and will follow them, as it must follow all the requirements of TSCA, whether or not they are codified in regulation. Indeed, EPA clearly explained in the Inventory Rule preamble that the Agency "will review" the relevant confidentiality claims "as specified by TSCA section 14(g)(1)." 82 Fed. Reg. at 37,527. And EPA broadly stated its agreement with EDF that TSCA § 14, 15 U.S.C. § 2613, applies to CBI claims under the Inventory Rule, in response to EDF comments. Therefore, EDF has provided no basis for its assertion that it will be injured by EPA's incorporation of 40 C.F.R. Part 2 into the Inventory Rule. Nor can EDF show that

any alleged injury would be remedied if EPA were to codify the relevant TSCA § 14, 15 U.S.C. § 2613, requirements.

EDF submits only a "theory of *future* injury[, which] is too speculative to satisfy the well-established requirement that threatened injury must be 'certainly impending.'" *Clapper*, 586 U.S. at 401 (quoting *Whitmore v. Arkansas*, 495 U.S. 149, 158 (1990); emphasis in original). EDF's "injury" is nothing more than unsubstantiated worry that when EPA does make a determination on a confidentiality claim asserted in a Notice of Activity Form, (a) it will not do so within 90 days, (b) if EPA denies a claim, it will not inform the claimant of its right to appeal, and (c) it will not make non-confidential aspects of its confidential business information determinations public. EDF Br. at 49-52. That EPA will not comply with relevant statutory provisions regarding confidentiality determinations is nothing more than unsupported speculation, which is insufficient for Article III standing. EPA had no obligation to import existing and independent TSCA requirements into the Inventory Rule, and the mere fact that EDF apparently would have preferred that it do so cannot provide a basis for standing.

B. EDF Has Not Shown Any Conflict Between the Inventory Rule and TSCA § 14, 15 U.S.C. § 2613.

EDF appears to have conflated the absence of additional, unnecessary cross-references to TSCA § 14, 15 U.S.C. § 2613, in the Inventory Rule's regulatory text with an affirmative statement by EPA of willful intent to disregard EPA's other

statutory obligations. EDF's insinuations of impending conflicts are belied by EPA's actual statements in the Rule preamble and Response to Comments.

As described above, EPA's Inventory Rule states that confidentiality claims will be "treated and disclosed in accordance with 40 CFR part 2, subpart B," 40 C.F.R. § 710.37(b). EDF misreads this statement by EPA as implying that the Agency will not review or decide confidentiality claims in accordance with the requirements in TSCA § 14(g)(1), 15 U.S.C. § 2613(g)(1). *See* EDF Br. at 49-51. To the contrary, EPA clearly explained in the Inventory Rule preamble that the Agency "will review" the relevant confidentiality claims "as specified by TSCA section 14(g)(1)." 82 Fed. Reg. at 37,527. EPA furthermore made its position clear in its response to EDF's comments, stating, in part, "EPA agrees that the requirements of TSCA section 14 generally apply to CBI claims made in this collection." JA183 (Response to Comments); *see also* JA186. In any event, the 40 C.F.R. part 2, subpart B, regulations are fully compatible with the review requirements set forth in TSCA, and do not in any way inhibit EPA from meeting its statutory review obligations. *See* 40 C.F.R. §§ 2.204(a)(2), 2.306(d).

EDF next vaguely asserts that EPA's 40 C.F.R. part 2 regulations are "not reconciled" with the TSCA § 14(g)(2), 15 U.S.C. § 2613(g)(2), claim denial and appeal process. *See* EDF Br. at 51. EDF again fails to identify any actual conflict between EPA's regulations and TSCA. In fact, the applicable regulation, 40 C.F.R. § 2.306(e),

provides for a 30-day period to seek appeal of a claim denial by bringing an action in an appropriate district court, consistent with TSCA § 14(g)(2), 15 U.S.C. § 2613(g)(2).

Moreover, to the extent EDF's brief can be construed as also arguing that the "administrative comment" process described in 40 C.F.R. § 2.204 has not been "reconciled . . . with EPA's obligation to determine claims within the 90-day window," EDF Br. at 51, EPA notes that the comment (i.e., substantiation) process described in section 2.204(e) is irrelevant here. This is because all relevant claimants have already been notified, via Federal Register publication of the Inventory Rule (codified at 40 C.F.R. § 710.37) and TSCA itself, of their obligation to substantiate claims asserted in conjunction with Inventory Rule reporting, of the deadline for such substantiation, and of EPA's routine review of many such claims. *See* 40 C.F.R. § 2.204(d)(1)(i), (e)(5).

EDF's third allegation, that the absence of a specific provision in EPA's Inventory Rule or general confidential business information regulations to address an unrelated, generally-applicable statutory requirement in TSCA § 26(j), 15 U.S.C. § 2625(j), pertaining to the availability of nonconfidential information to the public, will somehow inexorably result in EPA's noncompliance with the statute, is similarly unavailing. *See* EDF Br. at 51-52. TSCA and the other environmental statutes contain numerous requirements that EPA has not codified in regulation, but that does not make them any the less binding. Again, EDF has made no showing that EPA's regulations conflict with the statute.

In sum, TSCA § 14, 15 U.S.C. § 2613, applies of its own force, and EPA does not read either the Inventory Rule or the 40 C.F.R. part 2 regulations as conflicting in any way with it. EPA's reading of its own regulations is entirely reasonable.

IV. EPA's Assignment of Unique Identifiers Is a Separate Matter That Is Irrelevant to the Inventory Rule.

While the Lautenberg Act made many revisions to TSCA requiring further EPA action, the Inventory Rule is limited in scope to addressing the statutory mandates of TSCA §§ 8(b)(4)(A)-(B) and 8(b)(5), 15 U.S.C. § 2607(b)(4)(A)-(B) and 8(b)(5). EPA has done so, but EDF argues that EPA should have addressed additional elements of the Lautenberg Act in this rulemaking. Specifically, EDF argues that the Rule should also have implemented a purported requirement relating to the assignment of unique identifiers to confidential chemical identities. EDF asserts that "when EPA identifies an active chemical on the Inventory as 'confidential,' EPA must provide a 'unique identifier' for that chemical." EDF Br. at 52-53. EDF appears to argue that unique identifiers must be assigned in the first version of the Inventory containing active-inactive designations, and that such assignment must be effectuated by the Inventory Rule. *See* EDF Br. at 52-54. However, EDF misreads the statutory requirements for EPA's Inventory Rule.

TSCA § 8(b)(7)(B), 15 U.S.C. § 2607(b)(7)(B), provides that EPA shall make available to the public the unique identifier (commonly referred to as "UID") "assigned under section 14" for each chemical substance on the confidential portion

of the Inventory. In turn, TSCA § 14, 15 U.S.C. § 2613, provides for unique identifiers to be assigned once EPA "approves" a confidentiality claim. 15 U.S.C. § 2613(g)(4)(A)(i). Instead, EDF appears to argue that EPA must assign a unique identifier to each confidential chemical substance identified as active on the initial update to the Inventory—without regard to whether EPA has reviewed and approved the confidentiality claim for that specific chemical identity. EDF Br. at 52-53

EDF's approach is not required by the statute. Under TSCA § 8(b)(4)(C), 15 U.S.C. § 2607(b)(4)(C), EPA need not even publish its plan for reviewing these confidentiality claims until one year after it publishes the first list of active/inactive substances, and its actual review of confidentiality claims need not begin until after that plan has been finalized. Thus, the statutory scheme set forth by Congress clearly does not require the first list of active/inactive substances to include unique identifiers for all chemical identities claimed as confidential. Rather, TSCA provides for the assignment of unique identifiers to specific chemical identities only once the relevant confidentiality claims have been reviewed and approved by EPA. 15 U.S.C. § 2613(g)(4).

EDF also attempts to argue that EPA failed to properly respond to its comments regarding unique identifiers. EDF Br. at 54. This is simply not the case. EDF's twentieth comment on the proposed rule stated:

> **20. EPA needs to make clear that the public information requirements of section 8(b)(7) apply to chemical identity claims under both sections 8 and 14.**

> Section 8(b)(7) delineates a number of requirements, including some that are applicable to Inventory listings made pursuant to that subsection, under which authority the Inventory is established and required to be maintained. While the placement of these requirements under section 8(b) is logical given its applicability to Inventory listings, some of the requirements are broader than just Inventory listings. *For example, EPA is required to make public unique identifiers and other identifying information on chemicals that may or may not be done through the Inventory.*
>
> EPA's rule should specify how such information will be made available, and the timeframes and deadlines that will apply to EPA's updates of both the Inventory and other required public listings. . . .

JA111 (emphasis in italics added). EPA did address this comment, stating, in part, that "EPA agrees that the requirements of TSCA section 14 generally apply to confidentiality claims made in this collection," and explained that EPA's review of these chemical identity confidentiality claims will be addressed in a separate rulemaking pursuant to TSCA § 8(b)(4)(C), 15 U.S.C. § 2607(b)(4)(C). JA183 (Response to Comments). EDF's attempt to make a single example given into "a major substantive comment," to which EPA was required to respond in greater detail is unpersuasive. *Sierra Club v. EPA*, 863 F.3d. 834, 838 (D.C. Cir. 2017); *see also City of Vernon v. FERC*, 845 F.2d 1045, 1047 (D.C. Cir. 1988) (an agency is not required to make "silk purse responses to sow's ear arguments").

V. EPA Reasonably Exempted Export-Only Manufacturers From Reporting Under the Inventory Rule Because Such Manufacturing Is Exempt From Premanufacture Notice Requirements.

Under TSCA § 12(a), 15 U.S.C. § 2611(a), Congress created an exemption for export-only chemicals from most TSCA provisions.[5] Among other things, this provision exempts any person manufacturing a chemical substance solely for export from the United States from the requirement to submit a Premanufacture Notice, so long as specified requirements are met. 15 U.S.C. § 2611(a)(1); *see also* 40 C.F.R. § 720.30(e). On its face, though, the exemption created under TSCA § 12, 15 U.S.C. § 2611, does not exempt export-only chemical substances from the requirements of TSCA § 8, 15 U.S.C. § 2607, which authorizes EPA to require various recordkeeping and reporting, and which also creates the TSCA Inventory. *Id.* at § 2611(a)(1).

When the Lautenberg Act amended TSCA § 8(b), 15 U.S.C. § 2607(b), to update the Inventory with active/inactive designations, Congress stated that EPA "shall require manufacturers, and may require processors, . . . to notify the Administrator . . . of each chemical substance on the [TSCA Inventory] that . . . has [been] *manufactured or processed for a nonexempt commercial purpose*" leading up to the Lautenberg Act. 15 U.S.C. § 2607(b)(4)(A)(i) (emphasis added). Congress similarly limited forward-looking reporting requirements to those persons that intend to manufacture or process an inactive substance "for a nonexempt commercial

[5] This provision was not substantively amended by the Lautenberg Act.

purpose." 15 U.S.C. § 2607(b)(5)(B)(i). Congress did not define the term "nonexempt commercial purpose" in TSCA. However, as explained by EPA in its proposed rule, the term had previously been used by EPA to refer to circumstances under which premanufacture reporting, *see* 15 U.S.C. § 2604, and/or chemical data reporting, *see* 15 U.S.C. § 2607(a), has been required. *See* 82 Fed. Reg. at 4259.

In the Inventory Rule, EPA interpreted manufacturing "for a nonexempt commercial purpose" to exclude various commercial activities that have been exempted from premanufacture notice requirements due to their limited nature and purpose, including manufacture or processing of a substance solely for export from the United States.[6] *See* 82 Fed. Reg. at 37,523, 37,528, 37,541. EPA explained that many of the chemical substances manufactured for an exempt commercial purpose have never been listed on the Inventory due to similar exemptions from premanufacture notice requirements, and are therefore already excluded from reporting under the Rule (consistent with TSCA § 8(b)(4), 15 U.S.C. § 2607(b)(4), which only requires reporting for "each chemical substance on the list published under paragraph (1)," i.e., the Inventory). *See* 82 Fed. Reg. at 37,523, 37,528. However, EPA recognized that in certain cases, chemical substances manufactured by a company under a premanufacture notice exemption may nevertheless have been

[6] Except, however, where the Administrator has made a finding described in TSCA § 12(a)(2), 15 U.S.C. § 2611(a)(2).

added to the Inventory voluntarily, or may subsequently have been added to the Inventory by another manufacturer. *See id.* It is these types of scenarios in which the exemptions established in the Rule at 40 C.F.R. § 710.27(a) become pivotal for determining a manufacturer's obligation to report under the Inventory Rule.

With regard to the export-only exemption, EPA explained in the Rule preamble and Response to Comments:

> While TSCA section 12(a)(1) authorizes EPA to include substances manufactured or processed solely for export in TSCA section 8 reporting, EPA construes manufacturing or processing solely for export to be an exempt commercial purpose, given that section 12(a)(1) broadly exempts such activities from other TSCA provisions, including [Premanufacture Notice] requirements under section 5.

82 Fed. Reg. at 37,528; JA155 (Response to Comments).

EDF, however, reads TSCA § 12(a)(1), 15 U.S.C. § 2611(a)(1), as *prohibiting* EPA from exempting export-only manufacturers and processors from any reporting requirement authorized under TSCA § 8, 15 U.S.C. § 2607, including notifications under the Inventory Rule.[7] EDF Br. at 55-56. This reading is not supported by the text of the statute. Rather, TSCA § 12(a)(1), 15 U.S.C. § 2611(a)(1), mandates an exemption for export-only substances from most TSCA provisions, but does not extend this categorical mandate to TSCA § 8, 15 U.S.C. § 2607, as a general matter.

[7] To the extent that EDF is arguing that EPA is required to add export-only substances to the Inventory which were not previously listed on the Inventory at all, that is clearly beyond the scope of TSCA § 8(b)(4), 15 U.S.C. § 2607(b)(4), and this rulemaking.

Here the Lautenberg Act specifically and independently establishes an exemption within the text of TSCA § 8(b), 15 U.S.C. § 2607(b), that is reasonably construed to encompass manufacture solely for export. EPA reasonably determined that in limiting the new reporting requirements under TSCA § 8(b)(4)-(5), 15 U.S.C. § 2607(b)(4)-(5), to manufacture and processing "for a nonexempt commercial purpose," Congress intended to incorporate many of the same reporting exemptions that already exist pursuant to other sections of TSCA, including §§ 5(h) and 12(a). JA154-156. Indeed, EDF agrees that the interpretation EPA adopted in the proposed rule of "nonexempt commercial purpose" was "plausible," based on the "commonly-accepted usage at the time that TSCA was amended, in 2016." EDF Br. at 55. EDF also concedes that other exemptions EPA added in the final rule "are likely within EPA's discretion." EDF Br. at 15. EDF provides no basis to conclude that EPA's exemption for exports is based on any less plausible of an interpretation of nonexempt commercial purpose, or is any less within EPA's discretion.

EDF also argues that EPA failed to meet notice-and-comment requirements because "the proposed rule never suggested that EPA might exempt reporting for export-only chemicals." EDF Br. at 57. This is not correct. The proposed rule discussed the scope of reporting exemptions related to manufacturing for an exempt commercial purpose, and specifically referenced exemptions from premanufacture reporting requirements under TSCA § 5, 15 U.S.C. § 2604, as one of the bases for determining that a manufacturer was exempt from the notification requirements

under this rule. 82 Fed. Reg. at 4259. EPA solicited public comment on this issue in the proposed rule. *See id.* at 4262.

During the rulemaking, "[s]everal commenters indicated that EPA should clarify the activities for which notification is not required under the rule." 82 Fed. Reg. at 37,527. In particular, several commenters requested that EPA confirm that chemicals manufactured for export are exempt from these requirements. *See* JA075, JA118, JA068, JA047, JA089. In response to these comments, EPA added language to 40 C.F.R. § 710.27(a)(4) stating that chemical substances manufactured solely for export are exempt from filing a Notice of Activity to EPA. Thus, not surprisingly, stakeholders understood that, when EPA proposed certain reporting exemptions based on existing regulatory provisions—including existing Premanufacture Notice exemptions—EPA might in the final rule adjust the specific exemptions provided based on the same logic. *See Nat. Res. Def. Council, Inc. v. Thomas*, 838 F.2d at 1243. EPA appropriately changed its proposed regulation in response to the comments received.

CONCLUSION

For the foregoing reasons, the Petition for Review should be denied.

Respectfully submitted,

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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 Garamond, 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 12,927, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/Phillip R. Dupré
PHILLIP R. DUPRÉ

CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia 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/ Phillip R. Dupré
PHILLIP R. DUPRÉ

STATUTORY AND REGULATORY ADDENDUM

Addendum Contents

15 U.S.C. § 2604……..ADD1

United States Code Annotated
Title 15. Commerce and Trade
Chapter 53. Toxic Substances Control (Refs & Annos)
Subchapter I. Control of Toxic Substances (Refs & Annos)

15 U.S.C.A. § 2604

§ 2604. Manufacturing and processing notices

Effective: June 22, 2016
Currentness

(a) In general

(1)(A) Except as provided in subparagraph (B) of this paragraph and subsection (h), no person may--

(i) manufacture a new chemical substance on or after the 30th day after the date on which the Administrator first publishes the list required by section 2607(b) of this title, or

(ii) manufacture or process any chemical substance for a use which the Administrator has determined, in accordance with paragraph (2), is a significant new use.

(B) A person may take the actions described in subparagraph (A) if--

(i) such person submits to the Administrator, at least 90 days before such manufacture or processing, a notice, in accordance with subsection (d), of such person's intention to manufacture or process such substance and such person complies with any applicable requirement of, or imposed pursuant to, subsection (b), (e), or (f); and

(ii) the Administrator--

(I) conducts a review of the notice; and

(II) makes a determination under subparagraph (A), (B), or (C) of paragraph (3) and takes the actions required in association with that determination under such subparagraph within the applicable review period.

(2) A determination by the Administrator that a use of a chemical substance is a significant new use with respect to which notification is required under paragraph (1) shall be made by a rule promulgated after a consideration of all relevant factors, including--

(A) the projected volume of manufacturing and processing of a chemical substance,

(B) the extent to which a use changes the type or form of exposure of human beings or the environment to a chemical substance,

(C) the extent to which a use increases the magnitude and duration of exposure of human beings or the environment to a chemical substance, and

(D) the reasonably anticipated manner and methods of manufacturing, processing, distribution in commerce, and disposal of a chemical substance.

(3) Review and determination

Within the applicable review period, subject to section 2617 of this title, the Administrator shall review such notice and determine--

(A) that the relevant chemical substance or significant new use presents an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the Administrator shall take the actions required under subsection (f);

(B) that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of the relevant chemical substance or significant new use; or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

in which case the Administrator shall take the actions required under subsection (e); or

(C) that the relevant chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, in which case the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for a significant new use.

(4) Failure to render determination

(A) Failure to render determination

If the Administrator fails to make a determination on a notice under paragraph (3) by the end of the applicable review period and the notice has not been withdrawn by the submitter, the Administrator shall refund to the submitter all applicable fees charged to the submitter for review of the notice pursuant to section 2625(b) of this title, and the Administrator shall not be relieved of any requirement to make such determination.

(B) Limitations

(i) A refund of applicable fees under subparagraph (A) shall not be made if the Administrator certifies that the submitter has not provided information required under subsection (b) or has otherwise unduly delayed the process such that the Administrator is unable to render a determination within the applicable review period.

(ii) A failure of the Administrator to render a decision shall not be deemed to constitute a withdrawal of the notice.

(iii) Nothing in this paragraph shall be construed as relieving the Administrator or the submitter of the notice from any requirement of this section.

(5) Article consideration

The Administrator may require notification under this section for the import or processing of a chemical substance as part of an article or category of articles under paragraph (1)(A)(ii) if the Administrator makes an affirmative finding in a rule under paragraph (2) that the reasonable potential for exposure to the chemical substance through the article or category of articles subject to the rule justifies notification.

(b) Submission of information

(1)(A) If (i) a person is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance, and (ii) such person is required to submit information for such substance pursuant to a rule, order, or consent agreement under section 2603 of this title before the submission of such notice, such person shall submit to the Administrator such information in accordance with such rule, order, or consent agreement at the time notice is submitted in accordance with subsection (a)(1).

(B) If--

(i) a person is required by subsection (a)(1) to submit a notice to the Administrator, and

(ii) such person has been granted an exemption under section 2603(c) of this title from the requirements of a rule or order under section 2603 of this title before the submission of such notice,

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such person may not, before the expiration of the 90 day period which begins on the date of the submission in accordance with such rule of the information the submission or development of which was the basis for the exemption, manufacture such substance if such person is subject to subsection (a)(1)(A)(i) or manufacture or process such substance for a significant new use if the person is subject to subsection (a)(1)(A)(ii).

(2)(A) If a person--

(i) is required by subsection (a)(1) to submit a notice to the Administrator before beginning the manufacture or processing of a chemical substance listed under paragraph (4), and

(ii) is not required by a rule, order, or consent agreement under section 2603 of this title before the submission of such notice to submit information for such substance,

such person may submit to the Administrator information prescribed by subparagraph (B) at the time notice is submitted in accordance with subsection (a)(1).

(B) Information submitted pursuant to subparagraph (A) shall be information which the person submitting the information believes shows that--

(i) in the case of a substance with respect to which notice is required under subsection (a)(1)(A)(i), the manufacture, processing, distribution in commerce, use, and disposal of the chemical substance or any combination of such activities will not present an unreasonable risk of injury to health or the environment, or

(ii) in the case of a chemical substance with respect to which notice is required under subsection (a)(1)(A)(ii), the intended significant new use of the chemical substance will not present an unreasonable risk of injury to health or the environment.

(3) Information submitted under paragraph (1) or (2) of this subsection or under subsection (e) shall be made available, subject to section 2613 of this title, for examination by interested persons.

(4)(A)(i) The Administrator may, by rule, compile and keep current a list of chemical substances with respect to which the Administrator finds that the manufacture, processing, distribution in commerce, use, or disposal, or any combination of such activities, presents or may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors.

(ii) In making a finding under clause (i) that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or any combination of such activities presents or may present an unreasonable risk of injury to health or the environment, the Administrator shall consider all relevant factors, including--

(I) the effects of the chemical substance on health and the magnitude of human exposure to such substance; and

(II) the effects of the chemical substance on the environment and the magnitude of environmental exposure to such substance.

(B) The Administrator shall, in prescribing a rule under subparagraph (A) which lists any chemical substance, identify those uses, if any, which the Administrator determines, by rule under subsection (a)(2), would constitute a significant new use of such substance.

(C) Any rule under subparagraph (A), and any substantive amendment or repeal of such a rule, shall be promulgated pursuant to the procedures specified in section 553 of Title 5.

(c) Extension of review period

The Administrator may for good cause extend for additional periods (not to exceed in the aggregate 90 days) the period, prescribed by subsection (a) or (b). Subject to section 2613 of this title, such an extension and the reasons therefor shall be published in the Federal Register and shall constitute a final agency action subject to judicial review.

(d) Content of notice; publications in the Federal Register

(1) The notice required by subsection (a) shall include--

(A) insofar as known to the person submitting the notice or insofar as reasonably ascertainable, the information described in subparagraphs (A), (B), (C), (D), (F), and (G) of section 2607(a)(2) of this title, and

(B) in such form and manner as the Administrator may prescribe, any information in the possession or control of the person giving such notice which are related to the effect of any manufacture, processing, distribution in commerce, use, or disposal of such substance or any article containing such substance, or of any combination of such activities, on health or the environment, and

(C) a description of any other information concerning the environmental and health effects of such substance, insofar as known to the person making the notice or insofar as reasonably ascertainable.

Such a notice shall be made available, subject to section 2613 of this title, for examination by interested persons.

(2) Subject to section 2613 of this title, not later than five days (excluding Saturdays, Sundays and legal holidays) after the date of the receipt of a notice under subsection (a) or of information under subsection (b), the Administrator shall publish in the Federal Register a notice which--

(A) identifies the chemical substance for which notice or information has been received;

(B) lists the uses of such substance identified in the notice; and

(C) in the case of the receipt of information under subsection (b), describes the nature of the tests performed on such substance and any information which was developed pursuant to subsection (b) or a rule, order, or consent agreement under section 2603 of this title.

A notice under this paragraph respecting a chemical substance shall identify the chemical substance by generic class unless the Administrator determines that more specific identification is required in the public interest.

(3) At the beginning of each month the Administrator shall publish a list in the Federal Register of (A) each chemical substance for which notice has been received under subsection (a) and for which the applicable review period has not expired, and (B) each chemical substance for which such period has expired since the last publication in the Federal Register of such list.

(e) Regulation pending development of information

(1)(A) If the Administrator determines that--

(i) the information available to the Administrator is insufficient to permit a reasoned evaluation of the health and environmental effects of a chemical substance with respect to which notice is required by subsection (a); or

(ii)(I) in the absence of sufficient information to permit the Administrator to make such an evaluation, the manufacture, processing, distribution in commerce, use, or disposal of such substance, or any combination of such activities, may present an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use; or

(II) such substance is or will be produced in substantial quantities, and such substance either enters or may reasonably be anticipated to enter the environment in substantial quantities or there is or may be significant or substantial human exposure to the substance,

the Administrator shall issue an order, to take effect on the expiration of the applicable review period, to prohibit or limit the manufacture, processing, distribution in commerce, use, or disposal of such substance or to prohibit or limit any combination of such activities to the extent necessary to protect against an unreasonable risk of injury to health or the environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use, and the submitter of the notice may commence manufacture of the chemical substance, or manufacture or processing of the chemical substance for a significant new use, including while any required information is being developed, only in compliance with the order.

(B) An order may not be issued under subparagraph (A) respecting a chemical substance (i) later than 45 days before the expiration of the applicable review period, and (ii) unless the Administrator has, on or before the issuance of the order, notified, in writing, each manufacturer or processor, as the case may be, of such substance of the determination which underlies such order.

(C) Repealed. Pub.L. 114-182, Title I, § 5(5)(C), June 22, 2016, 130 Stat. 458

(2) Repealed. Pub.L. 114-182, Title I, § 5(5)(D), June 22, 2016, 130 Stat. 458

(f) Protection against unreasonable risks

(1) If the Administrator determines that a chemical substance or significant new use with respect to which notice is required by subsection (a) presents an unreasonable risk of injury to health or environment, without consideration of costs or other nonrisk factors, including an unreasonable risk to a potentially exposed subpopulation identified as relevant by the Administrator under the conditions of use, the Administrator shall, before the expiration of the applicable review period, take the action authorized by paragraph (2) or (3) to the extent necessary to protect against such risk.

(2) The Administrator may issue a proposed rule under section 2605(a) of this title to apply to a chemical substance with respect to which a finding was made under paragraph (1)--

(A) a requirement limiting the amount of such substance which may be manufactured, processed, or distributed in commerce,

(B) a requirement described in paragraph (2), (3), (4), (5), (6), or (7) of section 2605(a) of this title, or

(C) any combination of the requirements referred to in subparagraph (B).

Such a proposed rule shall be effective upon its publication in the Federal Register. Section 2605(d)(3)(B) of this title shall apply with respect to such rule.

(3)(A) The Administrator may issue an order to prohibit or limit the manufacture, processing, or distribution in commerce of a substance with respect to which a finding was made under paragraph (1). Such order shall take effect on the expiration of the applicable review period.

(B) The provisions of subparagraph (B) of subsection (e)(1) shall apply with respect to an order issued under subparagraph (A).

(C) Redesignated (B)

(D) Repealed. Pub.L. 114-182, Title I, § 5(6)(C)(iv), June 22, 2016, 130 Stat. 459

(4) Treatment of nonconforming uses

Not later than 90 days after taking an action under paragraph (2) or (3) or issuing an order under subsection (e) relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A)

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or (B), the Administrator shall consider whether to promulgate a rule pursuant to subsection (a)(2) that identifies as a significant new use any manufacturing, processing, use, distribution in commerce, or disposal of the chemical substance that does not conform to the restrictions imposed by the action or order, and, as applicable, initiate such a rulemaking or publish a statement describing the reasons of the Administrator for not initiating such a rulemaking.

(5) Workplace exposures

To the extent practicable, the Administrator shall consult with the Assistant Secretary of Labor for Occupational Safety and Health prior to adopting any prohibition or other restriction relating to a chemical substance with respect to which the Administrator has made a determination under subsection (a)(3)(A) or (B) to address workplace exposures.

(g) Statement on Administrator finding

If the Administrator finds in accordance with subsection (a)(3)(C) that a chemical substance or significant new use is not likely to present an unreasonable risk of injury to health or the environment, then notwithstanding any remaining portion of the applicable review period, the submitter of the notice may commence manufacture of the chemical substance or manufacture or processing for the significant new use, and the Administrator shall make public a statement of the Administrator's finding. Such a statement shall be submitted for publication in the Federal Register as soon as is practicable before the expiration of such period. Publication of such statement in accordance with the preceding sentence is not a prerequisite to the manufacturing or processing of the substance with respect to which the statement is to be published.

(h) Exemptions

(1) The Administrator may, upon application, exempt any person from any requirement of subsection (a) or (b) to permit such person to manufacture or process a chemical substance for test marketing purposes--

(A) upon a showing by such person satisfactory to the Administrator that the manufacture, processing, distribution in commerce, use, and disposal of such substance, and that any combination of such activities, for such purposes will not present any unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator for the specific conditions of use identified in the application, and

(B) under such restrictions as the Administrator considers appropriate.

(2)(A) The Administrator may, upon application, exempt any person from the requirement of subsection (b)(2) to submit information for a chemical substance. If, upon receipt of an application under the preceding sentence, the Administrator determines that--

(i) the chemical substance with respect to which such application was submitted is equivalent to a chemical substance for which information has been submitted to the Administrator as required by subsection (b)(2), and

(ii) submission of information by the applicant on such substance would be duplicative of information which has been submitted to the Administrator in accordance with such subsection,

the Administrator shall exempt the applicant from the requirement to submit such information on such substance. No exemption which is granted under this subparagraph with respect to the submission of information for a chemical substance may take effect before the beginning of the reimbursement period applicable to such information.

(B) If the Administrator exempts any person, under subparagraph (A), from submitting information required under subsection (b)(2) for a chemical substance because of the existence of previously submitted information and if such exemption is granted during the reimbursement period for such information, then (unless such person and the persons referred to in clauses (i) and (ii) agree on the amount and method of reimbursement) the Administrator shall order the person granted the exemption to provide fair and equitable reimbursement (in an amount determined under rules of the Administrator)--

(i) to the person who previously submitted the information on which the exemption was based, for a portion of the costs incurred by such person in complying with the requirement under subsection (b)(2) to submit such information, and

(ii) to any other person who has been required under this subparagraph to contribute with respect to such costs, for a portion of the amount such person was required to contribute.

In promulgating rules for the determination of fair and equitable reimbursement to the persons described in clauses (i) and (ii) for costs incurred with respect to a chemical substance, the Administrator shall, after consultation with the Attorney General and the Federal Trade Commission, consider all relevant factors, including the effect on the competitive position of the person required to provide reimbursement in relation to the persons to be reimbursed and the share of the market for such substance of the person required to provide reimbursement in relation to the share of such market of the persons to be reimbursed. For purposes of judicial review, an order under this subparagraph shall be considered final agency action.

(C) For purposes of this paragraph, the reimbursement period for any previously submitted information for a chemical substance is a period--

(i) beginning on the date of the termination of the prohibition, imposed under this section, on the manufacture or processing of such substance by the person who submitted such information to the Administrator, and

(ii) ending--

(I) five years after the date referred to in clause (i), or

(II) at the expiration of a period which begins on the date referred to in clause (i) and is equal to the period which the Administrator determines was necessary to develop such information,

whichever is later.

(3) The requirements of subsections (a) and (b) do not apply with respect to the manufacturing or processing of any chemical substance which is manufactured or processed, or proposed to be manufactured or processed, only in small quantities (as defined by the Administrator by rule) solely for purposes of--

(A) scientific experimentation or analysis, or

(B) chemical research on, or analysis of such substance or another substance, including such research or analysis for the development of a product,

if all persons engaged in such experimentation, research, or analysis for a manufacturer or processor are notified (in such form and manner as the Administrator may prescribe) of any risk to health which the manufacturer, processor, or the Administrator has reason to believe may be associated with such chemical substance.

(4) The Administrator may, upon application and by rule, exempt the manufacturer of any new chemical substance from all or part of the requirements of this section if the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of such chemical substance, or that any combination of such activities, will not present an unreasonable risk of injury to health or the environment, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified by the Administrator under the conditions of use.

(5) The Administrator may, upon application, make the requirements of subsections (a) and (b) inapplicable with respect to the manufacturing or processing of any chemical substance (A) which exists temporarily as a result of a chemical reaction in the manufacturing or processing of a mixture or another chemical substance, and (B) to which there is no, and will not be, human or environmental exposure.

(6) Immediately upon receipt of an application under paragraph (1) or (5) the Administrator shall publish in the Federal Register notice of the receipt of such application. The Administrator shall give interested persons an opportunity to comment upon any such application and shall, within 45 days of its receipt, either approve or deny the application. The Administrator shall publish in the Federal Register notice of the approval or denial of such an application.

(i) Definitions

(1) For purposes of this section, the terms "manufacture" and "process" mean manufacturing or processing for commercial purposes.

(2) For purposes of this chapter, the term "requirement" as used in this section shall not displace any statutory or common law.

(3) For purposes of this section, the term "applicable review period" means the period starting on the date the Administrator receives a notice under subsection (a)(1) and ending 90 days after that date, or on such date as is provided for in subsection (b)(1) or (c).

