ORAL ARGUMENT HAS NOT YET BEEN SCHEDULED

No. 17-1201

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

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ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; AND SCOTT PRUITT, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Defendants-Appellees,

AMERICAN CHEMISTRY COUNCIL; et al.,
Intervenors for Respondents.

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PETITION FOR REVIEW OF RULE OF U.S. ENVIRONMENTAL PROTECTION AGENCY, "TSCA INVENTORY NOTIFICATION (ACTIVE-INACTIVE) REQUIREMENTS," 82 FED. REG. 37,520 (AUG. 11, 2017)

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# PETITIONER ENVIRONMENTAL DEFENSE FUND'S PRINCIPAL BRIEF

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## CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to D.C. Circuit Rule 28(a)(1), Petitioner Environmental Defense Fund certifies as follows:

### (A) Parties and Amici

Petitioner: Environmental Defense Fund

Respondents: The United States Environmental Protection Agency and Scott Pruitt, in his official capacity as Administrator of the United States Environmental Protection Agency.

Intervenors: American Chemistry Council, American Fuel & Petrochemical Manufacturers, American Petroleum Institute, Chamber of Commerce of the United States of America, Society of Chemical Manufacturers and Affiliates, American Coatings Association, American Coke and Coal Chemicals Institute, American Forest & Paper Association, EPS Industry Alliance, IPC International, Inc., doing business as IPC – Association Connecting Electronics Industries, National Association of Chemical Distributors, National Association of Manufacturers, National Mining Association, and Polyurethane Manufacturers Association.

### (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). JA:___-___.

**(C) Related Cases**

Petitioner is not aware of any related cases as defined by D.C. Circuit Rule 28(a)(1)(C).

DATED: March 6, 2018 Respectfully submitted,

/s/ Robert P. Stockman

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## RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Federal Rule of Appellate Procedure 26.1 and D.C. Circuit Rule 26.1, petitioner Environmental Defense Fund (EDF) makes the following disclosures:

Non-Governmental Corporate Party to this Action: Environmental Defense Fund (EDF).

Parent Corporations: None.

Publicly Held Company that Owns 10% or More of Party's Stock: None.

Party's General Nature and Purpose: EDF, a corporation organized and existing under the laws of the State of New York, is a national nonprofit organization that links science, economics, and law to create innovative, equitable, and cost-effective solutions to society's most urgent environmental problems.

DATED: March 6, 2018

Respectfully submitted,

/s/ Robert P. Stockman

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## GLOSSARY

| | |
|---|---|
| APA | Administrative Procedure Act |
| CBI | Confidential Business Information |
| EDF | Environmental Defense Fund |
| EPA | Environmental Protection Agency |
| FOIA | Freedom of Information Act |
| TSCA | Toxic Substances Control Act |

## STATEMENT OF JURISDICTION

On September 1, 2017, Environmental Defense Fund (EDF) filed a timely petition for review of the final rule of the Environmental Protection Agency entitled "TSCA Inventory Notification (Active-Inactive) Requirements," published at 82 Fed. Reg. 37,520 (Aug. 11, 2017). This Court has jurisdiction pursuant to the Toxic Substances Control Act (TSCA) § 19(a)(1)(A). 15 U.S.C. § 2618(a)(1)(A).

## INTRODUCTION

TSCA § 8(b) has long required EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." 15 U.S.C. § 2607(b)(1). The Inventory now lists about 85,600 chemicals, but no one knows how many are in active commerce today. EPA conceals the specific chemical identity of approximately 17,800 of these chemicals because those identities were claimed to be confidential under TSCA § 14 and Exemption 4 of the Freedom of Information Act (FOIA).[1] Most of these claims have never been reviewed by EPA to determine if they are warranted. It is often difficult or impossible for public interest groups and researchers to identify or study a chemical and understand its uses, exposures, and health and environmental effects when the specific chemical identity is unknown. *See, e.g.*, Addendum pp.3-9,

[1] For purposes of TSCA, TSCA § 14 governs claims for confidentiality under Exemption 4 of FOIA. 5 U.S.C. § 552(b)(4).

153-62, 253-63.[2] In contrast, if the identity is known, EDF, other public interest groups, and researchers can identify, develop, and analyze information about the chemical through a variety of means. *See, e.g.*, Addendum pp.3-9, 153-62, 253-63.

In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act) to address these problems among others. The Lautenberg Act required EPA to issue a rule to update the Inventory under TSCA § 8(b) in several major ways. 15 U.S.C. § 2607(b)(4). First, EPA must identify which chemicals on the Inventory have been actively manufactured in the United States for a nonexempt commercial purpose within the last ten years. Second, EPA must review the "existing" confidentiality claims for specific chemical identities of such active chemicals that manufacturers or processors seek to maintain. If no manufacturer or processor seeks to maintain a claim of confidentiality for the specific chemical identity of an active chemical, then EPA must disclose the identity on the Inventory. After reviewing the existing claims that manufacturers or processors seek to maintain—under TSCA's new, more-stringent disclosure standards set forth in TSCA § 14—EPA must disclose those identities of active chemicals for which no valid claim exists.

On August 11, 2017, EPA published the Inventory rule in the Federal Register. EPA-HQ-OPPT-2016-0426-0070 (JA:___-___). In this rule, EPA

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[2] Citations to the Addendum are to the separately bound standing addendum.

adopted a number of positions which violate the statutory text, are arbitrary and capricious, or violate notice-and-comment requirements. The resulting rule will not disclose some information that EDF would otherwise use to learn more about chemicals and their uses, exposures, and health and environmental effects.

## STATEMENT OF THE ISSUES

1. The Inventory rule must require manufacturers or processors that "seek[] to *maintain* an *existing* claim for protection against disclosure of the specific chemical identity" to submit a request to maintain that claim. 15 U.S.C. § 2607(b)(4)(B)(ii) (emphases added). Here, EPA allowed a manufacturer or processor to assert confidentiality claims even if that manufacturer or processor had never asserted such a claim in the past, as long as someone had. But confidentiality claims are person-specific, and a person cannot "maintain an existing claim" if the person has never asserted the claim before.
2. The Lautenberg Act significantly revised TSCA § 14, governing claims for confidentiality. Section 14 now requires that confidentiality claims must meet numerous substantive and procedural requirements beyond those required by FOIA Exemption 4. The final rule fails to incorporate several of § 14's requirements and directs EPA to follow its general FOIA regulations.

It therefore directs EPA to process confidentiality claims without complying with all of the requirements in TSCA § 14.

3. TSCA § 8(b)(7) requires EPA to provide certain information to the public about chemicals on the confidential portion of the Inventory, such as the chemical's "unique identifier." The final rule does not implement all of the public information requirements of § 8(b)(7).

4. EPA must require notification of manufacture for a nonexempt commercial purpose during the 10-year look-back period. In the final rule, EPA exempted manufacturing or processing a chemical solely for export because TSCA § 12 exempts such chemicals from many provisions of TSCA. But the statutory exemption in § 12 expressly does not apply to reporting under § 8, as here.

## STATEMENT OF THE CASE

### A. The Inventory prior to the Lautenberg Act

#### 1. EPA created the Inventory and it steadily grew to over 85,000 chemicals.

When Congress first passed TSCA in 1976, Congress directed EPA to "compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States." Pub. L. No. 94-469, § 8(b)(1), 90 Stat. 2003, 2028 (1976) (codified as amended at 15 U.S.C. § 2607(b)(1)). EPA initially compiled a list of approximately 62,000 chemicals. This list of chemicals

became known as the TSCA Chemical Substance Inventory (hereinafter, the Inventory).

The Inventory continued to grow over the years as new chemicals came onto the market. Under TSCA § 5, a person generally cannot manufacture a chemical that is not on the Inventory without notifying EPA 90 days beforehand. 15 U.S.C. §§ 2604, 2602(11). EPA then had an opportunity to review the chemical. Pub. L. No. 94-469, § 5, 90 Stat. 2003, 2012-20 (codified as amended at 15 U.S.C. § 2604).[3] After EPA's review process, a person had to provide a notice of the chemical's first production or importation for a nonexempt commercial purpose. 40 C.F.R. § 720.102(b). EPA would then add the chemical to the Inventory. 15 U.S.C. § 2607(b)(1). As a result, new chemicals have steadily been added to the Inventory over the years.

**2. EPA reviewed few confidentiality claims, and the Inventory now includes 17,800 chemicals with concealed specific chemical identities.**

When EPA promulgated the regulations requiring reporting for the Inventory, EPA allowed manufacturers and processors to assert a claim for confidentiality of the specific chemical identity. 42 Fed. Reg. 64,572, 64,590-93 (Dec. 23, 1977). Those regulations required that "[a]ny claims of confidentiality

[3] The Lautenberg Act substantially amended TSCA § 5, but those changes are beyond the scope of this particular case.

must accompany the information at the time it is submitted to EPA." *Id.* at 64,579 (codified at 40 C.F.R. § 710.7(b)). Similarly, EPA's general regulations governing confidential business information (CBI) under FOIA required that people submitting any confidential information assert claims of confidentiality at the time of submission or risk disclosure of that information. 41 Fed. Reg. 36,902, 36,907, 36,919 (Sept. 1, 1976) (codified at 40 C.F.R. § 2.203(b)-(c)).

Whenever EPA received a claim for confidentiality for the specific chemical identity, EPA would not place the specific chemical identity on the Inventory and would instead publish a generic name for the chemical in an Appendix to the Inventory. *See* 42 Fed. Reg. at 64,574.

EPA received many claims for confidentiality, but it reviewed very few. It also appears that, if a specific chemical identity was claimed confidential when reported by one person, then EPA would conceal that information even if a different person submitted the same information without any claim for confidentiality. *See* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). Thus, EPA would sometimes conceal information received from a person even if that person did not assert that it was confidential.

Numerous government-sponsored studies of EPA's management of confidentiality claims under TSCA have found that EPA systematically failed to scrutinize claims and that many claims, once scrutinized, lacked merit. *See, e.g.*,

Hampshire Research Associates, Inc., *Influence of CBI Requirements on TSCA Implementation* (March 1992), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2002-0054-0074. For example, the Hampshire Report found that, when substantially identical information was submitted under TSCA and another federal statute, the confidentiality claim rate under TSCA was at least 10 times higher than the rate under the other federal statute; "more probably, the claim rate [was] more than a thousand times higher under TSCA." *Id.* at 41. In addition, in those few cases where EPA reviewed claims, EPA found up to 50% to be invalid. "When submitters of [these] claims were challenged, EPA prevailed *in every case*." *Id.*

In 2005, the Government Accountability Office reported that the "EPA official responsible for initiating challenges to confidentiality claims told us that EPA challenges about 14 such claims each year, and that the chemical companies withdraw nearly all of the claims challenged." GAO, *Chemical Regulation, Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program* 33 (June 2005), https://www.gao.gov/assets/250/246667.pdf.

### B. The Lautenberg Act

In 2016, Congress passed the Lautenberg Act, substantially amending TSCA. Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. §§ 2601-2627). Congress included several provisions designed to update and

revise the Inventory. Congress also included numerous provisions requiring greater disclosure of information to the public.

### 1. The Lautenberg Act required that EPA revise the Inventory and review existing claims of confidentiality for specific chemical identities.

TSCA § 8(b)(4)(A)(i) required EPA to promulgate the regulation at issue in this case:

> Not later than 1 year after the date of enactment of the [Lautenberg Act], [EPA], by rule, shall require manufacturers, and may require processors, subject to the limitations under subsection (a)(5)(A), to notify [EPA], by not later than 180 days after the date on which the final rule is published in the Federal Register, of each chemical substance on the [Inventory] that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the [Lautenberg Act].

15 U.S.C. § 2607(b)(4)(A)(i).

TSCA requires that EPA "shall designate chemical substances for which notices are received [under this rule] to be active substances" on the Inventory. *Id.* § 2607(b)(4)(A)(ii). EPA "shall designate chemical substances for which no notices are received *** to be inactive substances" on the Inventory. *Id.* § 2607(b)(4)(A)(iii). Going forward, TSCA provides a notice requirement and process for a manufacturer or processor to move chemicals from the inactive portion of the Inventory to the active portion. *Id.* § 2607(b)(5)(B)(i).

In promulgating this rule, EPA has to "maintain" the Inventory, "which shall include a confidential portion and a nonconfidential portion consistent with this section and section 14." *Id.* § 2607(b)(4)(B)(i). EPA must "require any manufacturer or processor of a chemical substance on the confidential portion of the [Inventory] that seeks to maintain an existing claim for protection against disclosure of the specific chemical identity" to submit a request to maintain that claim. *Id.* § 2607(b)(4)(B)(ii). EPA must "require the substantiation of those claims pursuant to section 14 and in accordance with the review plan described" below. *Id.* § 2607(b)(4)(B)(iii). EPA must also "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 *** from the confidential portion of the [Inventory] to the nonconfidential portion." *Id.* § 2607(b)(4)(B)(iv).

The Lautenberg Act also required EPA to disclose certain information to the public about the chemicals on the Inventory. *Id.* § 2607(b)(7). We describe these provisions *infra* at pp.19-22, 52-55.

In addition to the Inventory rule, EPA must also "promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities *** that are asserted" within one year "after the date on which [EPA] compiles the initial list of active substances." 15 U.S.C. § 2607(b)(4)(C). In establishing that

review plan, EPA shall "require *** all manufacturers or processors asserting claims *** to substantiate the claim, in accordance with section 14." *Id.* § 2607(b)(4)(D)(i).

EPA must "complete reviews of all [such asserted] claims" for nondisclosure within five years of EPA "compil[ing] the initial list of active substances." *Id.* § 2607(b)(4)(E)(i). EPA "may extend the deadline for completion of the reviews for not more than 2 additional years." *Id.* § 2607(b)(4)(E)(ii)(I).

### 2. The Lautenberg Act revised the confidentiality requirements of TSCA § 14.

The Lautenberg Act also substantially revised TSCA § 14, 15 U.S.C. § 2613, which governs the disclosure of information covered by FOIA Exemption 4. Exemption 4 provides that FOIA does not require disclosure of "matters that are trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). TSCA § 14, in turn, provides that, "[e]xcept as provided in this section, [EPA] shall not disclose information that is exempt from disclosure pursuant to [Exemption 4]—(1) that is reported to, or otherwise obtained by, [EPA] under [TSCA]; and (2) for which the requirements of subsection (c) are met." 15 U.S.C. § 2613(a). As a result, EPA can now only protect information from disclosure if each of two separate standards is met. To refuse to disclose information, EPA has to establish that information falls within

FOIA Exemption 4. In addition, EPA also has to determine that the information meets the requirements of TSCA § 14(c).

In turn, TSCA § 14(c) provides additional requirements for confidentiality, creating a three-step procedure for asserting and substantiating a claim. At the first step, a person must assert the claim and make a statement supporting the claim when the person submits the information. 15 U.S.C. § 2613(c)(1)(A).

> An assertion of a claim *** 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.

*Id.* § 2613(c)(1)(B).

The second procedural step is substantiation. TSCA § 14(c)(2) exempts certain information from the substantiation requirements. *See id.* § 2613(c)(2). For all other information, "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim." *Id.* § 2613(c)(3). EPA has recognized that the substantiation requirement is not conditional upon a future rulemaking. 82 Fed. Reg. 6522, 6523 (Jan. 19, 2017).

At the third procedural step, EPA must review certain claims and make a decision on the claims within 90 days. EPA must review "all" CBI claims for specific chemical identities (with one exception not relevant here). 15 U.S.C. § 2613(g)(1)(C)(i). Section 14 imposes strict deadlines on this process. For new CBI claims asserted after the passage of the Lautenberg Act, except for those under (c)(2), EPA must "not later than 90 days after the receipt of a claim" "review and approve, approve in part and deny in part, or deny the claim or request." *Id.* § 2613(g)(1)(A). If EPA denies the claim, EPA must notify the claimant, who then has a short time period to file a lawsuit against EPA challenging disclosure. *Id.* § 2613(g)(2)(A), (D). Under TSCA § 26(j), EPA must make its confidentiality determinations available to the public. *Id.* § 2625(j)(1).

### C. Factual History

EPA proposed the Inventory Rule on January 13, 2017. EPA-HQ-OPPT-2016-0426-0001 (JA:___-___). The proposed rule required any person who manufactured a chemical during the 10-year lookback period to report that manufacture with a few specified exemptions. EPA-HQ-OPPT-2016-0426-0001 p.12 (JA:___). The proposed rule also included detailed substantiation questions for any confidentiality claim. EPA-HQ-OPPT-2016-0426-0001 pp.14-15 (JA:___-___). Among other things, these substantiation questions would require

claimants to make some showing that the information met all four criteria specified in TSCA § 14(c)(1)(B).

EDF submitted comments on the proposed rule. EPA-HQ-OPPT-2016-0426-0064 (JA:___-____). As relevant here, EDF explained that "CBI claims are company-specific" and EPA should not allow persons that had not previously asserted a claim to assert a new claim through the Inventory notification process. EPA-HQ-OPPT-2016-0426-0064 p.13 (JA:___). EDF noted that this section of the law only permitted requests to "maintain an existing claim," so persons that had not previously asserted CBI claims could not do so here, though they arguably could do so through the § 14 process requiring immediate substantiation and review within 90 days. EPA-HQ-OPPT-2016-0426-0064 p.13 (JA:___). EDF also contended that the rule needed to incorporate the provisions of TSCA § 14 governing the "assertion, substantiation and review of CBI claims" into the rule. EPA-HQ-OPPT-2016-0426-0064 p.17 (JA:___); *see also* EPA-HQ-OPPT-2016-0426-0039 p.3 (JA:___). Finally, EDF contended that the Inventory rule needed to include how EPA would meet the public information requirements of TSCA § 8(b)(7), such as the "unique identifier" requirement for confidential chemicals. EPA-HQ-OPPT-2016-0426-0064 p.18 (JA:___).

EPA published the final rule on August 11, 2017. EPA-HQ-OPPT-2016-0426-0070 (JA:___-___). The preamble to the final rule stated that EPA would

still allow any person submitting a notice to assert a confidentiality claim for specific chemical identity, regardless of whether that person had ever claimed the identity merited confidential protection before. EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). The text of the final rule still failed to incorporate many of the substantive and procedural requirements of TSCA § 14 governing confidentiality claims. *See* EPA-HQ-OPPT-2016-0426-0070 pp.24-25 (JA:___-___) (codified at 40 C.F.R. § 710.37). Both the preamble and rule also failed to address how EPA would meet the "unique identifier" requirements of TSCA § 8(b)(7).

In addition, the final rule differed from the proposed rule in several major ways. *First*, EPA substantially revised and deleted substantiation questions, and in the process, EPA eliminated all of the questions which addressed one of the four required criteria for confidentiality under TSCA § 14(c)(1)(B). Unlike the proposed rule, the final rule contains *no* questions addressing whether the information could be readily discoverable through reverse engineering. *Compare* EPA-HQ-OPPT-2016-0426-0070 p.25 (JA:___), *with* 15 U.S.C. § 2613(c)(1)(B)(iv); *see also* EPA-HQ-OPPT-2016-0426-0087 pp.2-3 (JA:___-___). The resulting rule and disclosure forms allow people to submit confidentiality claims without substantiating this required criterion.

*Second*, the final rule created numerous additional exceptions and exemptions from the obligation to report manufacture during the lookback period.

*See, e.g.*, EPA-HQ-OPPT-2016-0426-0070 p.22 (JA:___). Some of these exemptions, while unwise, are likely within EPA's discretion. But EPA also exempted "[t]he manufacturing or processing of a chemical substance solely for export from the United States." EPA-HQ-OPPT-2016-0426-0070 p.22 (JA:___) (40 C.F.R. § 710.27). As explained below, this exemption is contrary to the statutory text governing export in TSCA § 12.

## SUMMARY OF ARGUMENT

With the Lautenberg Act, Congress substantially revised TSCA §§ 8 and 14, which govern the Inventory and confidentiality claims. Many of these amendments directed EPA to disclose more information to the public, emphasizing the public's right to know about chemicals in U.S. commerce. In promulgating the final rule, EPA repeatedly violated the statutory text and erred in favor of concealment instead of disclosure. EDF challenges four aspects of that rule.

*First*, the Lautenberg Act creates a five-year process to review the validity of *existing* claims for confidentiality for specific chemical identities, and the Act only allows manufacturers or processors to submit a confidentiality claim through that process if they "seek[] to *maintain* an *existing* claim for protection against disclosure of the specific chemical identity." 15 U.S.C. § 2607(b)(4)(B)(ii) (emphases added). Despite that plain language, EPA allowed a person to assert confidentiality claims even if that person had never asserted such a claim in the

past, as long as someone had. But confidentiality claims are person-specific, and a person does not have the ability to "maintain" an "existing claim" to something if the person never asserted a claim to it before. In addition, EPA's reasons for this approach are arbitrary and capricious.

*Second*, TSCA § 14 now requires that confidentiality claims must meet numerous substantive and procedural requirements beyond those required by FOIA Exemption 4. The final rule failed to incorporate several of § 14's substantive and procedural requirements, and the rule directs EPA to process confidentiality claims under EPA's general FOIA regulations which do not include these requirements. Thus, EPA's final rule states that certain information is entitled to confidential treatment even when it is not entitled to such treatment under TSCA § 14.

*Third*, TSCA § 8(b)(7) requires EPA to provide certain information to the public about chemicals on the confidential portion of the Inventory, such as the chemical's "unique identifier." The final rule does not implement all of the public information requirements of § 8(b)(7), and EPA failed to provide any rationale for refusing to do so. EPA also failed to respond to EDF's comment on this issue.

*Fourth*, EPA must require notification of manufacture for a "nonexempt commercial purpose during the 10-year" look-back period. 15 U.S.C. § 2607(b)(4)(A)(i). In the final rule, EPA exempted manufacturing or processing a chemical solely for export because TSCA § 12 exempts such chemicals from many

provisions of TSCA. But the statutory exemption in § 12 expressly does not apply to reporting under § 8, as here. Under the plain text, export-only chemicals are nonexempt for purposes of the Inventory.

## STANDARD OF REVIEW

EPA has adopted some interpretations that are so inconsistent with the text and structure of TSCA that they are impermissible under the *Chevron* framework. *See Kingdomware Techs., Inc. v. United States*, 136 S. Ct. 1969, 1979 (2016) (citing *Chevron U.S.A. Inc. v. NRDC*, 467 U.S. 837, 843-44 (1984)). Under *Chevron* step one, the court must determine "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842. If so, then the court and the agency must "give effect to the unambiguously expressed intent of Congress." *Id.* at 842-43. If the court determines that "the statute is silent or ambiguous with respect to the specific issue," then under *Chevron* step two, "the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.* at 843.

In some places, EPA's reasoning is "arbitrary, capricious, [or] an abuse of discretion" under the Administrative Procedure Act (APA), 5 U.S.C. § 706(2)(A), because it "entirely fail[s] to consider an important aspect of the problem, offer[s] an explanation for its decision that runs counter to the evidence before the agency, or is so implausible that it could not be ascribed to a difference in view or the

product of agency expertise." *Motor Vehicle Mfrs. Ass'n of the U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983).

Finally, EPA violated the notice-and-comment requirements of the APA on several issues because the final rule deviated from the proposed rule in ways that are not a "logical outgrowth" of the proposed rule. *CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079-80 (D.C. Cir. 2009).

## ARGUMENT

### I. Standing

EDF has standing in this case because the Inventory Rule fails to disclose information as required under the Lautenberg Act, and EDF suffers an informational injury from the nondisclosure of the information. Standing requires that the litigant has "suffered a concrete and particularized injury that is either actual or imminent, that the injury is fairly traceable to the defendant, and that it is likely that a favorable decision will redress that injury." *Massachusetts v. EPA*, 549 U.S. 497, 517 (2007).

In informational standing cases, a petitioner suffers an "injury in fact" when an agency action cuts the petitioner off from "information which must be publicly disclosed pursuant to a statute." *FEC v. Akins*, 524 U.S. 11, 21 (1998); *see also Pub. Citizen v. U.S. Dep't of Justice*, 491 U.S. 440, 449-50 (1989). "Following *Akins*, this circuit has recognized that 'a denial of access to information can work

an 'injury in fact' for standing purposes, at least where a statute (on the claimants' reading) requires that the information be publicly disclosed and there is no reason to doubt their claim that the information would help them.'" *Friends of Animals v. Jewell*, 824 F.3d 1033, 1040-41 (D.C. Cir. 2016) (quoting *Ethyl Corp. v. EPA*, 306 F.3d 1144, 1148 (D.C. Cir. 2002)). This inquiry does not require a statutory mandate to release information to a targeted group of individuals; rather, the mandate can apply to the general public. *See Akins*, 524 U.S. at 24.

In regards to the informational injury, a harm is sufficient so long as there "is no reason to doubt" that the information would help the petitioner. *Ethyl Corp.*, 306 F.3d at 1148 (quoting *Akins*, 524 U.S. at 21). An injury is possible even if the information sought does not yet exist, or could be claimed CBI. *See id.* at 1150 (requiring the promulgation of procedures not yet devised, and recognizing that it is not relevant whether some of the information may be protected by CBI).

### A. The Inventory Rule withholds information from the public that is required to be disclosed under the Lautenberg Act.

TSCA states that EPA "shall *** publish a list of each chemical substance which is manufactured or processed in the United States." 15 U.S.C. § 2607(b)(1). The Lautenberg Act expressly mandates that EPA disclose to the public certain information for each chemical that is on that Inventory. *Id.* § 2607(b)(7). EPA "shall make available to the public each specific chemical identity" for each chemical listed on the non-confidential portion of the Inventory. *Id.*

§ 2607(b)(7)(A). EPA shall also disclose whether those chemicals are "active or inactive," *i.e.*, whether they have been manufactured or processed in the United States in the last ten years. *Id.* Additionally, for each chemical on the confidential portion of the Inventory, EPA "shall make available to the public *** the unique identifier." *Id.* § 2607(b)(7)(B).

In addition, if EPA does not receive a request "to maintain an existing claim" for confidentiality for "specific chemical identity," then EPA must move the chemical "to the nonconfidential portion" of the Inventory. *Id.* § 2607(b)(4)(B)(iv). As noted above, EPA must then disclose the specific chemical identity. *Id.* § 2607(b)(7)(A), (C)(i). Finally, as explained *infra* at pp.44-52, EPA has a duty to review certain claims for confidentiality under the substantive and procedural standards of TSCA § 14, and EPA "shall make available to the public" all its "determinations" on those reviews. *Id.* § 2625(j)(1).

These provisions all "clearly create[] a right to information upon which a claim of informational standing may be predicated." *Friends of Animals*, 824 F.3d at 1041. EDF's inability to obtain this information is fairly traceable to EPA's actions in promulgating the flawed Rule, because, despite these mandates to make information publicly available, EPA's final Inventory Rule failed to do so in numerous ways.

*First*, as explained *infra* at pp.30-43, the Inventory Rule permitted manufacturers and processors to assert *new* confidentiality claims through the TSCA § 8(b) process in order to keep chemicals on the confidential portion of the Inventory. EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). In doing so, the rule allows more persons to assert confidentiality claims without providing concurrent substantiation and without requiring EPA review within 90 days of assertion. The result is that more chemicals with unsubstantiated confidentiality claims will remain, for up to five to seven years,[4] on the confidential portion of the Inventory with the specific chemical identities concealed.

*Second*, the rule allows persons to assert confidentiality claims without meeting all of the substantive and procedural requirements of TSCA § 14. As a result, EPA will allow some claims that do not meet the substantive requirements of TSCA § 14 and thus EPA will fail to disclose nonconfidential information. In addition, the rule does not require EPA to make its determinations public, as required by law. *See* 15 U.S.C. § 2625(j)(1).

*Third*, the Inventory Rule also failed to require that unique identifiers be assigned for chemicals listed on the confidential portion of the Inventory, and as a result, unique identifiers are not being made publicly available.

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[4] *See* 15 U.S.C. § 2607(b)(4)(E)(i).

*Fourth*, EPA eliminated the requirement to report chemicals that are manufactured or processed solely for export. *See* EPA-HQ-OPPT-2016-0426-0070 p.22 (JA:___). Thus, EPA will not publicly disclose any information on an entire category of chemicals that are manufactured or processed in the United States.

**B. EDF has been harmed by the failure to disclose this information.**

EPA's actions have harmed EDF because the Inventory Rule limits EDF's access to information that is guaranteed by the Lautenberg Act. *See, e.g.*, 15 U.S.C. § 2607(b)(7). This harm establishes standing. No additional injury is necessary in order to establish informational standing in this case because this is precisely "the type of harm Congress sought to prevent by requiring disclosure" under the Lautenberg Act. *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016); *see also Waterkeeper Alliance v. EPA*, 853 F.3d 527, 534 (D.C. Cir. 2017) (concluding that the reduction of reporting requirements under CERCLA, on its own, was a sufficient injury for standing because it deprived the public of information "which would otherwise be required"); *Zivotofsky v. Sec'y of State*, 444 F.3d 614, 617 (D.C. Cir. 2006) ("[T]he requester's circumstances—why he wants the information, what he plans to do with it, what harm he suffered from the failure to disclose—are irrelevant to his standing.").

The Inventory Rule further harms EDF because having access to the information guaranteed under the Lautenberg Act is crucial to EDF's research and advocacy activities. *See Friends of Animals*, 824 F.3d at 1041 (finding informational injury where the non-disclosed information would help the party "engage in related advocacy efforts"). EDF is a membership organization that relies on science, economics, and law to protect and restore the quality of our air, water, and other natural resources. Addendum pp.426-28 (Stith Decl.). Among other goals, EDF seeks to "[s]ignificantly reduce exposure to high-risk chemicals in consumer products, water and food," in part, by "significantly expand[ing] actionable information on chemical risks." Addendum pp.27-28, 2-3. EDF's goals of gaining actionable information about chemicals to reduce the risks they present to health and the environment align perfectly with TSCA's statutory purposes. *See* 15 U.S.C. § 2601.

**1. EDF's research, advocacy, and administrative efforts are harmed by EPA's failure to disclose information.**

The flaws in the Inventory Rule thwart EDF's efforts because EPA will conceal available information on chemicals, in particular, the specific chemical identities of chemicals. EDF's research and advocacy activities rely on accessing a number of databases that contain use, hazard, and exposure information on chemicals, but they are only searchable by the specific chemical identities. Addendum pp.8-9 (Denison Decl.). EDF also consults the list of chemicals

registered under the European Union's REACH program, including those identified as "substances of very high concern," but EDF needs the specific chemical identity to consult that list. Addendum p.7. If the specific chemical identity does not appear on the nonconfidential portion of the Inventory, EDF cannot determine if the chemical is manufactured in the United States. Addendum p.7.

EDF has long used these public databases to track chemicals of high-concern, and EDF then educates its members and the public about those chemicals. Addendum pp.3-9. Over the years EDF has developed a number of extensive reports, such as *Toxic Ignorance*, *Toxics Across America*, and *Across the Pond*, that analyzed and presented available information on chemicals of high concern. Addendum pp.4-5, 32-150. For example, *Toxics Across America* used chemical production information collected by EPA to allow users to see whether high-concern chemicals were produced in their communities. Addendum pp.122-50. Each of these efforts was limited, however, to the information that was publicly available at the time and contained disclosures stating as much. Addendum pp.4-6. For example, when the specific chemical identities were concealed, EDF could not provide accurate reports on those confidential chemicals: EDF could not identify whether the chemical was produced in the United States or all of its producers, whether safety information was lacking, whether other authorities had identified

risk concerns for the chemical, or whether the chemical was produced in certain communities. *See* Addendum pp.4-7.

EDF will likely publish additional reports on chemicals in the future relying on chemical information collected and disclosed by EPA. Addendum p.8. EDF would be able to provide more comprehensive reports on chemicals if EPA placed more chemicals on the nonconfidential portion of the Inventory, revealing their specific chemical identities. Addendum p.8. Similarly, EDF needs to know if export-only chemicals are manufactured or processed in the United States to determine and report on whether there could be exposures to those chemicals in the United States or abroad. In addition, if EPA denies some confidentiality claims accompanying the notices reporting manufacture or processing of chemicals, it would allow EDF to determine who was manufacturing or processing those chemicals. Addendum pp.5, 136.

EDF and our collaborators also need the specific chemical identity to apply structure-based predictive approaches to characterize chemical hazards and exposures. Addendum pp.153-59 (McPartland Decl.). EDF has used specific chemical identities to develop reports on safer chemical innovations. Addendum pp.157-59, 195-250. Specific chemical identity is also highly valuable for conducting environmental monitoring and biomonitoring for a particular chemical. Addendum pp.159-62, 253-57. EPA's withholding of this information will reduce

EDF's ability to conduct and use the results of these analyses. EDF's past practice of studying chemicals based on this type of information confirms that EDF has a concrete interest in this information and that EDF will likely use this type of information in the future.

For example, knowledge of certain specific chemical identities enabled EDF to collect information on levels of exposure. Addendum pp.253-56 (McCormick Decl.). EDF has conducted two projects to further its understanding of individual exposures by having its members and others wear silicone wristbands that can detect exposure to over 1,400 *known* chemicals. Addendum pp.254-56, 269-326. EDF could not test for chemicals whose specific chemical identities were unknown. Addendum p.256. EDF uses this type of exposure information to educate the public about their potential chemical exposure and to advocate for measures to reduce chemical exposure. Addendum pp.255-256, 269-326. In the future, these analyses could be more robust and provide greater educational value if EDF was able to screen for additional chemicals that were previously confidential.

EDF also requires the information guaranteed by the Lautenberg Act to effectively participate in administrative processes under TSCA, as well as to engage in political advocacy on these issues. *See Friends of Animals*, 824 F.3d at 1041. In order to engage in TSCA § 5 and § 6 processes—which govern new

chemicals and existing chemicals respectively—EDF relies on publicly available information on chemicals to provide comments. *See, e.g.*, Addendum pp.257-63, 360-98; *see also Ethyl Corp.*, 306 F.3d at 1147-48 (depriving a party of potentially helpful information for developing products was a sufficient injury). Knowledge of specific chemical identities allows EDF to draw comparisons between chemicals and identify potential risks presented by similarly structured chemicals. Addendum pp.154-57, 257-58. EDF would be able to use this information when commenting on new chemicals and when commenting on which existing chemicals should be selected for prioritization and risk evaluation. Addendum pp.257-63. EDF would also be able to use this information when submitting petitions under TSCA § 21. Addendum pp.261-62, 400-21.

**2. EDF is harmed by EPA's failure to disclose unique identifiers for confidential chemicals.**

Even if the specific chemical identity remains confidential, at a minimum, it is critical for EDF to know a chemical's unique identifier in order to fully engage in its TSCA related activities (though knowing specific chemical identities would serve these purposes as well). The system of unique identifiers introduced in the Lautenberg Act gives the public the ability to connect publicly available use, hazard, exposure, and other information on a chemical even when the chemical's specific chemical identity is confidential. *See* 15 U.S.C. § 2613(g)(4)(A)(ii).

The Lautenberg Act requires that the Inventory "shall make available to the public *** the unique identifier *** and, if applicable, premanufacture notice case number for each chemical *** for which a claim of confidentiality was received." *Id.* § 2607(b)(7)(B). Once EDF has the unique identifier and the premanufacture number, EDF can identify all non-confidential information on the chemical that is linked to that unique identifier and premanufacture number, which would reveal extensive information to EDF. *See* Addendum pp.258-62. For example, when EDF received this type of identifying information about certain brominated phthalates, it allowed us to find information in their premanufacture public files (including health and safety studies), 40 C.F.R. § 720.95, that revealed numerous serious health concerns. Addendum pp.259-61. EDF relied on that information when commenting. Addendum pp.261, 379-82. Similarly, EDF would be able to use the unique identifier to find all § 8(e) notices—which report information about risk to health and the environment—for a confidential chemical to compile all such information reported for that chemical. EDF would also be able to compare the risks identified in those notices to EPA's analyses of the potential risks of the chemical when it was reviewed under the § 5 new chemical program, to see whether those risks were not identified or underestimated in that earlier review.

### C. This Court can redress this harm.

If EDF succeeds on the merits, this Court can vacate the rule in part and remand to EPA with directions to revise the regulation to provide the required information. EDF will then receive the information that must be disclosed under TSCA. Specifically, EDF will likely receive many of the specific chemical identities of chemicals where the Rule unlawfully permitted persons to assert new claims without concurrent substantiation and immediate review. Past studies have shown that many confidentiality claims are either withdrawn or found invalid when the submitter is required to substantiate or defend the claims. *See, e.g.*, Hampshire Research Associates, Inc., *Influence of CBI Requirements on TSCA Implementation* (March 1992), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2002-0054-0074.

EDF will also receive the information where EPA correctly denies confidentiality claims after following all of the substantive and procedural requirements of TSCA § 14. EDF will learn the unique identifiers (and corresponding premanufacture notice numbers) of all the active chemicals listed on the confidential portion of the Inventory. Finally, EDF will also gain information, either the specific chemical identity or the unique identifiers, for chemicals that are manufactured in the United States solely for export.

## II. The final rule illegally allows manufacturers and processors to assert certain new claims for nondisclosure of specific chemical identities.

In the preamble to the final rule, EPA stated that any manufacturer or processor may assert a claim for confidentiality for a specific chemical identity through the § 8 process, regardless of whether that person (or a predecessor-in-interest) ever asserted such a claim of confidentiality before. *See* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___); EPA-HQ-OPPT-2016-0426-0086 pp.53-54 (JA:___-___). Under EPA's implementation, a person can now rely on *another* person's prior confidentiality claim for the specific chemical identity of a chemical, despite the fact that the claim and justification for each claim are person-specific. This effectively allowed persons to assert *new* confidentiality claims for a chemical identity using a process designed only to ensure the validity of claims previously asserted. This change allowed additional claims that will reduce the number of specific chemical identities disclosed by EPA.

EPA's approach is foreclosed by the plain language of § 8(b)(4)(B)(ii) and cannot be upheld under *Chevron* step-one. Even if the Court found the language ambiguous, EPA's interpretation is unreasonable at *Chevron* step-two.

### A. Allowing manufacturers and processors to assert new claims—based on <u>other</u> persons having asserted earlier claims—is contrary to TSCA's plain text and the relevant precedent governing confidentiality claims.

TSCA requires that EPA shall "require any manufacturer or processor of a chemical substance on the confidential portion of the [Inventory] 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 14 to submit a notice *** that includes such request." 15 U.S.C. § 2607(b)(4)(B)(ii). Textually, a manufacturer or processor may only "*maintain* an *existing claim* for protection against disclosure." *Id.* (emphases added). A person can only maintain an existing claim if the person (or their predecessor-in-interest) previously made the claim. As relevant here, "existing" means "in existence or operation at the time under consideration; current." *Oxford American Dictionary* 607 (3d ed. 2010). "Claim" means "a demand or request for something considered *one's* due *** a right or title to something." *Id.* at 318 (emphasis added). "[M]aintain" means to "cause or enable (a condition or state of affairs) to continue *** keep (something) at the same level or rate *** from latin *manu tenere* 'hold in the hand.'" *Id.* at 1055. A person does not "maintain" an "existing claim" to something if the person never asserted a claim to it before. EPA has redrafted the statute to allow persons to assert claims for any chemical on the confidential portion of the Inventory they

manufacture or process, but if Congress had meant to sweep so broadly, it would have said so.

EPA's theory appears to be that as long as *any* person has asserted that the specific chemical identity should be confidential, then a "claim for protection against nondisclosure" exists, and *any* person can now assert a claim for protection. EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). But EPA has provided *no* textual basis for its interpretation of the plain language: EPA has presented no argument for how a person asserting a claim it never made before is "maintain[ing] an existing claim." 15 U.S.C. § 2607(b)(4)(B)(ii). Agency interpretations need not be a model of clarity, but the agency must make a "reasonable attempt to grapple" with the statutory text as well as its purposes. *BP Energy Co. v. FERC*, 828 F.3d 959, 965 (D.C. Cir. 2016) (quoting *Council for Urological Interests v. Burwell*, 790 F.3d 212, 223 (D.C. Cir. 2015)). EPA's approach also has no basis in the broader precedent governing confidentiality and trade secrets.

The Lautenberg Act substantially amended TSCA's confidentiality provisions, and those provisions all reflect that confidentiality claims are person-specific for the information the person submitted. TSCA now provides that: "[a] person seeking to protect from disclosure any information *that person submits* under this Act *** shall assert to the Administrator *a claim* for protection from disclosure concurrent with submission of the information." 15 U.S.C.

§ 2613(c)(1)(A) (emphases added). A person may only assert "a claim" for protection of the information "that person submits"; a person has no right to demand confidentiality for information submitted by another person. Nor may a person rely on someone else to claim their information is confidential.

When asserting the claim, a person must also make numerous person-specific substantive assertions. 15 U.S.C. § 2613(c)(1)(B). A person must assert that the person has "taken reasonable measures to protect the confidentiality of the information" and the person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." *Id.* § 2613(c)(1)(B)(i), (iii). Thus, the Lautenberg amendments indicate claims are individual to the person asserting the claim. Indeed, the same information—such as specific chemical identity—could be confidential for one person and not for another, *e.g.*, if one person has taken sufficient steps to protect the information and another has not.

In addition, a person asserting a claim may always "withdraw[] the claim, in which case the information shall not be protected from disclosure under this section." *Id.* § 2613(e)(1)(B)(ii)(I). That provision does not give any other affected person a right to then assert the same claim; the information must be made public. And when a confidentiality claim expires after ten years, only the person who previously asserted the claim may reassert the claim. *Id.* § 2613(e)(2).

Similarly, only the person who asserted the claim receives notice of a denial of the claim and a right to appeal that claim to district court. *Id.* § 2613(g)(2)(A), (D).

EPA's own regulations have always provided protection to those persons who have "asserted an applicable claim" but not to persons who "failed to assert a claim covering the information after being informed by EPA that such failure could result in disclosure of the information to the public" or who "otherwise waived *** a claim covering the information." 40 C.F.R. §§ 2.204(c), 2.203(c). Here, the regulations governing the Inventory and other reporting requirements under TSCA have always informed manufacturers and processors that failure to assert a claim could result in disclosure. *See, e.g.*, 42 Fed. Reg. at 64,579 (codified at 40 C.F.R. § 710.7(b)); 40 C.F.R. § 720.80(d). EPA's regulations have never allowed one person to rely on another person's claim to avoid disclosure.

Moreover, the broader precedent regarding "trade secrets" and "confidential business information" is that they are person-specific, limited rights. *First*, if they are not person-specific—if numerous persons have the same information—there is a reasonable argument that the information no longer qualifies for these protections. *See, e.g.*, *Ruckelshaus v. Monsanto Co.*, 467 U.S. 986, 1002 (1984) ("Information that is public knowledge or that is generally known in an industry cannot be a trade secret."); *Kewanee Oil Co. v. Bicron Corp.*, 416 U.S. 470, 475 (1974) ("The subject of a trade secret must be secret, and must not be of public

knowledge or of a general knowledge in the trade or business."); *see also CNA Fin. Corp. v. Donovan*, 830 F.2d 1132, 1154 (D.C. Cir. 1987). In contrast, EPA's approach *strengthens* the protections for information precisely when the protection may be least appropriate.

If anything, when one person ceases to treat information as confidential, then the information ceases to be secret and its protection for other persons can no longer be justified. EPA recently acknowledged this natural consequence: "If another company reveals that they manufacture the substance for commercial purposes, such as in a non-CBI submission filed under TSCA, the chemical identity is no longer eligible for confidential protection, and a CBI claim for chemical identity would be denied upon evaluation." 83 Fed. Reg. 5623, 5624 (Feb. 8, 2018). While EPA's recent statement is correct, as explained more below, the record indicates that EPA has historically taken the opposite, illegal approach of concealing the non-confidential submission of the latter submitter.

*Second*, the nature of these rights is that they are a species of property held by individual persons. Allowing one person to assert a claim because a different person asserted a claim for the same information is inconsistent with the "exclusivity" that comes with this type of property right. *See, e.g.*, *Carpenter v. United States*, 484 U.S. 19, 26 (1987) ("Confidential information acquired or compiled by a corporation in the course and conduct of its business is a species of

property to which the *corporation has the exclusive right and benefit*.") (emphasis added) (quoting 3 W. Fletcher, *Cyclopedia of Law of Private Corporations* § 857.1, p.260 (rev. ed. 1986)).

*Third*, these property rights provide *limited* rights that do not allow one person to restrain another person from independently discovering or developing the same information; they are not patent rights. The fact that one person chooses to keep information secret provides it with no authority to limit a different person from disclosing the same information, as long as it is independently developed. *Kewanee*, 416 U.S. at 476 (Trade secret law "does not offer protection against discovery by fair and honest means, such as by independent invention, accidental disclosure, or by so-called reverse engineering."); *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 156 (1989). Conversely, a person cannot claim confidentiality for its information merely on the basis that another person treats the information as confidential.

### B. EPA's rationale for its interpretation is arbitrary and capricious.

EPA's interpretation is foreclosed by the statutory language under either step of *Chevron*, but even if permissible, EPA's reasoning to justify this rule is arbitrary and capricious. *See Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017).

*First*, in the actual regulatory text, EPA attempts to accomplish its goal by defining "[e]xisting claim for protection of specific chemical identity against disclosure" 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*." EPA-HQ-OPPT-2016-0426-0070 p.22 (JA:___) (to be codified at 40 C.F.R. § 710.23) (emphasis added). But EPA's definition pointedly avoids indicating *who* had to have asserted the claim. It raises the question of how a person asserting a claim that the person is making for the first time *now* can be considered to have asserted a claim prior to June 22, 2016. EPA appears to simply assume that so long as some person made a confidentiality claim earlier, then a person making a claim now is asserting the same claim as the earlier person did. But EPA does not even explicitly articulate that theory. EPA provides a policy reason for preferring this approach, EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___), but EPA's policy concern does not justify "redraft[ing] the statutory boundaries set by Congress." *Loan Syndications & Trading Ass'n v. SEC*, 2018 U.S. App. LEXIS 3068, *23 (D.C. Cir. Feb. 9, 2018).

*Second*, EPA justified its decision by suggesting that, absent its approach, only the "original" claimant could assert a claim for nondisclosure. *See* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). EPA incorrectly stated that, if a person did not originally report the identity, they "therefore were not in a position to assert a

CBI claim for that chemical identity." EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). EPA's statements are factually and legally incorrect.

Nothing barred manufacturers and processors from asserting confidentiality claims for specific chemical identity simply because another person had previously asserted a claim for that identity. Quite the opposite. Since the 1970s, if a person notified EPA about a chemical, then under EPA's regulations, the person had to assert a confidentiality claim contemporaneously or risk waiving the claim. 41 Fed. Reg. 36,902, 36,907 (1976); 40 C.F.R. § 2.203(a)(1)-(2). Those regulatory requirements did not include any exception for information that had previously been asserted as confidential by a different person.

Indeed, *if* EPA had correctly implemented its regulations, then EPA's regulations required 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. *First*, if a person manufactured the chemical before EPA compiled the original Inventory, the person should have reported it during the process compiling the original Inventory. When EPA promulgated the regulations requiring reporting for the Inventory, EPA allowed manufacturers and processors to assert a claim for confidentiality of the chemical identity. *See* 42 Fed. Reg. at 64,573-74, 64,590-93. Those regulations required that "[a]ny claims of confidentiality must accompany the information at the time it is submitted to

EPA." *Id.* at 64,579. "If no claim accompanies information at the time it is submitted to EPA, the information may be made public by EPA without further notice to the submitter. Failure to provide substantiation of any claim *** will be considered a waiver of the claim." *Id.*; *see also* 41 Fed. Reg. at 36,907, 36,919. Thus, anyone who reported to EPA *during* the creation of the original Inventory had an obligation to make a claim for confidentiality of chemical identity if they wished to preserve that claim.

*Second*, if a person began manufacturing a chemical *after* the Inventory was compiled, then the person had to notify EPA under TSCA § 5 prior to the manufacture of the chemical.[5] If the person was the first to manufacture the chemical, then they had to provide a pre-manufacture notice to EPA through the TSCA § 5 process, and the outcome of that process was that the chemical would be added to the Inventory. If they were not the first person to manufacture the chemical, then they still would need to have determined whether the chemical was already on the Inventory, first by examining the public portion of the Inventory and, if the chemical was not listed there, by asking EPA whether the chemical was on the confidential portion of the Inventory. To avoid unnecessary pre-manufacture notification under § 5, EPA allows manufacturers to submit a notice

[5] Under TSCA § 5, a person generally cannot manufacture a chemical that is not on the Inventory without notifying EPA 90 days beforehand. 15 U.S.C. § 2604(a)(1), 2602(11).

of *bona fide* intent to manufacture the chemical. 42 Fed. Reg. at 64,579; *see also* 40 C.F.R. § 720.25. If EPA determines that the manufacturer has a *bona fide* intent to manufacture, then EPA tells the inquiring manufacturer whether the chemical is on the confidential portion of the Inventory. If it is, then the manufacturer does not need to file a pre-manufacture notice under TSCA § 5. If it is not, then the manufacturer does.

Thus, 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 pre-manufacture notice (if the chemical was not on the Inventory), or both. The regulations governing submissions of *bona fide* intent and pre-manufacture notices also required that anyone asserting a claim of confidentiality for the chemical identity had to assert that claim at the time of submission. *See, e.g.*, 48 Fed. Reg. 21,722, 21,751 (May 13, 1983) (codified at 40 C.F.R. § 720.80(b)) ("Any claim of confidentiality must accompany the information when it is submitted to EPA."); 40 C.F.R. § 720.80(d); *see also* 44 Fed. Reg. 2242, 2275 (Jan. 10, 1979) (proposed rule); EPA-HQ-OPPT-2016-0426-0073 p.2 (JA:___).

In sum, as a matter of law, anyone who legally manufactured a confidential chemical *should have* notified EPA of that manufacture at some point in the past. In addition, if the person wanted to assert a claim of confidentiality, they were

legally required to assert it or risked waiving the claim. However, since EPA's practice apparently was to keep information confidential as long as *someone* had claimed that information confidential—even if no confidentiality claim was asserted with a particular submission of information—it is likely that people manufactured or processed confidential chemicals without ever asserting a claim for confidentiality, and EPA would have continued to conceal the chemical identity. EPA does not expressly admit to this practice, but it is the best explanation for EPA's (false) assertion that only the "original" claimant was in a position to assert a claim. *See* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___).

EPA also speculated that some persons might not have had an opportunity to assert a claim, due to "mergers, acquisitions, or other business events." EPA-HQ-OPPT-2016-0426-0086 p.54 (JA:___). This concern does not justify EPA's decision to allow persons to assert claims now based on claims asserted by other persons to which they have no relationship. Notably, allowing claims in the limited circumstances of mergers and acquisitions fits the statutory text—allowing persons to "maintain an existing claim"—whereas EPA's new interpretation does not. As a successor-in-interest, the person is maintaining the existing claim made before the merger or acquisition.

The administrative record provides no factual analysis of this issue. How many of the 17,800 confidential chemicals were notified to EPA by multiple

persons? How often did EPA choose to keep the specific chemical identity confidential even though someone had submitted that information without asserting any claim? Only EPA has access to the records which would give the public and the Court knowledge of the scope of this issue, but EPA chose not to provide any factual analysis or evidence. This Court has ruled that EPA acted arbitrarily and capricious when it provides "no evidence" in support of its decisions. *United States Sugar Corp. v. EPA*, 830 F.3d 579, 644 (D.C. Cir. 2016). Such a ruling is particularly appropriate when, as here, EPA is the sole entity with access to the records that could answer these factual questions.

*Third*, TSCA § 14 provides a separate mechanism for people to make *new* claims of confidentiality. 15 U.S.C. § 2613. In its rule, EPA arguably could have permitted manufacturers and processors to assert and concurrently substantiate new claims for confidentiality for specific chemical identities through that process, and EPA would then have had to review and rule on the new claims within 90 days, instead of within the five to seven years allotted to substantiating and reviewing "existing claims." *Compare* 15 U.S.C. § 2613(g)(1)(A), *with* 15 U.S.C. § 2607(b)(4)(E). There is ample evidence that when EPA reviews claims, it finds many are invalid, and persons withdraw many claims. *See, e.g.*, *supra* at pp.5-7. Thus, requiring that new claims would be subject to review within 90-days instead of five to seven years would have discouraged weak claims and resulted in much

faster disclosure to the public when claims were denied. EPA did not even consider this option to resolve its policy concerns.

## III. The final rule violates both the substantive and procedural requirements of TSCA § 14.

Regarding confidentiality claims, the final rule states that: "[e]xcept as set forth in this section, information claimed as confidential in accordance with this subsection will be treated and disclosed in accordance with 40 CFR part 2, subpart B." EPA-HQ-OPPT-2016-0426-0070 p.24 (JA:___) (to be codified at 40 C.F.R. § 710.37(b)). But "this section" and the rule then fail to incorporate all of the procedural and substantive requirements for confidentiality claims under TSCA §§ 8 and 14. Similarly, those requirements do not appear in subpart B; the subpart B regulations govern CBI under FOIA Exemption 4, and those regulations were all drafted prior to the Lautenberg Act. 40 C.F.R. §§ 2.201-2.311. As a result, they do not contain all of the requirements of TSCA §§ 8 and 14 as amended.

If EPA follows the regulation as written, EPA will commit numerous violations of the procedural and substantive requirements set forth in TSCA § 14. EPA's complete failure to implement these statutory requirements is contrary to the statutory text and is thus foreclosed under the *Chevron* framework. And since EPA failed to even acknowledge this issue (despite EDF's comments requesting that it do so), there is no interpretation to which the Court could defer.

### A. EPA refused to accept that TSCA § 8 repeatedly incorporates TSCA § 14 requirements for confidentiality claims.

In the final rule, EPA failed to implement many of the applicable § 14 requirements for confidentiality claims. But TSCA § 8(b)(4)(B)(i) expressly directs that: "[T]he Administrator shall—maintain the [Inventory], which shall include a confidential portion and a nonconfidential portion *consistent with* this section *and section 14*." 15 U.S.C. § 2607(b)(4)(B)(i) (emphases added). Congress expressly required that confidentiality claims be "consistent with *** section 14." *Id.* As another example, if a person seeks to move an inactive chemical to the active portion of the Inventory and "seeks to maintain an existing claim" for confidentiality, then the person must substantiate it "consistent with the requirements of section 14." *Id.* § 2607(b)(5)(B)(ii). There are numerous additional textual examples, but in sum, § 8 repeatedly states that confidentiality claims made under § 8 must be consistent with § 14. *See id.* § 2607. Moreover, TSCA § 14 governs *all* confidentiality claims for information submitted under TSCA on its own terms. *See id.* § 2613.

### B. The final rule fails to implement one of the substantive requirements for confidentiality claims under TSCA § 14.

The final rule completely fails to implement one of the substantive confidentiality standards of TSCA § 14. The final rule provides that confidentiality claims "will be treated and disclosed in accordance with 40 CFR

part 2, subpart B," EPA-HQ-OPPT-2016-0426-0070 p.24 (JA:___), and the subpart B regulations then provide that information "is entitled to confidential treatment" if it meets certain criteria, 40 C.F.R. § 2.208. But § 2.208 does not include one of the criteria required for confidentiality by TSCA § 14. TSCA § 14(c)(1)(B)(iv) requires that a claim for confidentiality must be accompanied by, among other things, "a statement that the person has *** a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c)(1)(B)(iv). In addition, TSCA also requires that, with certain exceptions, "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim." *Id.* § 2613(c)(3).

To implement these statutory requirements, EPA must require that persons asserting confidentiality claims provide *some* substantiation that the claimed information is not readily discoverable through reverse engineering. While perhaps not comprehensive, the proposed rule included several questions that would have required a claimant to make some showing that the information meets this requirement. *See* EPA-HQ-OPPT-2016-0426-0001 pp.14-15 (JA:___-___). For example: "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?" EPA-HQ-OPPT-2016-0426-0001 p.14

(JA:___). But in the final rule, EPA eliminated the questions that addressed this issue, and EPA did not even acknowledge the issue.

As a result, the final rule contains *no* questions which would require disclosure of evidence addressing whether the information would be readily discoverable through reverse engineering. *Compare* EPA-HQ-OPPT-2016-0426-0001 pp.14-15 (JA:___-___) (proposed rule), *with* EPA-HQ-OPPT-2016-0426-0070 p.25 (JA:___). EPA's notification forms also fail to seek any substantiation of this criterion. EPA-HQ-OPPT-2016-0426-0087 (JA:___-___). While EPA has some discretion to shape these questions, it cannot completely ignore required criteria for confidentiality claims.

EPA's final rule has, as a practical matter, removed the obligation to substantiate that confidential information must be "not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c)(1)(B)(iv). In addition, the incorporation of § 2.208 suggests that information "is entitled to confidential treatment" even if it does not meet this criterion. 40 C.F.R. § 2.208.

To be sure, the rule requires that persons asserting claims assert that they "have a reasonable basis to believe that the information is not readily discoverable through reverse engineering." EPA-HQ-OPPT-2016-0426-0070 p.25 (JA:___) (codified at 40 C.F.R. § 710.37(e)(4)). But, except for information identified in TSCA § 14(c)(2), the Lautenberg Act *both* requires that the person assert a claim

*and* separately requires that the person substantiate it: "a person asserting a claim *** shall substantiate the claim." 15 U.S.C. § 2613(c)(3). Congress set forth these duties in separate provisions, reflecting that substantiation requires more than simply assertion. If assertion were sufficient, then the obligation to substantiate would be rendered "a worthless addendum." *Citizens for Responsibility & Ethics in Wash. v. FEC*, 711 F.3d 180, 188 (D.C. Cir. 2013). Such an interpretation is impermissible. *Id.* ("It is *** a cardinal principle of statutory construction that we must give effect, if possible, to every clause and word of a statute.") (quoting *Williams v. Taylor*, 529 U.S. 362, 404 (2000)).

In addition, EPA's analysis violates the APA in two different ways. *First*, it is arbitrary and capricious because EPA has "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. Nothing in the record addresses substantiation of the requirement that confidential information must be "not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c)(1)(B)(iv). Indeed, the words "discoverable," "reverse," and "engineering" do not even appear in EPA's response to comments. EPA-HQ-OPPT-2016-0426-0086 (JA:___-___). EPA's sole explanation for its changes to the substantiation questions was that EPA sought "to more succinctly secure answers." EPA-HQ-OPPT-2016-0426-0086 p.55 (JA:___). But in seeking to be succinct, EPA has completely failed to inquire about one of the necessary criteria.

It is also arbitrary and capricious to completely fail to consider the *downsides* to not seeking this information.

*Second*, EPA's approach violates notice-and-comment because EDF and the public were never given an opportunity to comment on the incredibly scaled back substantiation questions, and EPA never responded to the comments it received that were relevant to this general point. The proposed rule contained eleven different substantiation questions for chemical identity claims and ten different substantiation questions for other confidentiality claims. EPA-HQ-OPPT-2016-0426-0001 pp.13-14 (JA:___-___). Many of these questions included follow-up questions. These questions probed different important aspects of confidentiality claims, to ensure they had a sound basis in fact. *See also* EPA-HQ-OPPT-2016-0426-0008; EPA-HQ-OPPT-2016-0426-0009 (JA:___-___).

The final rule reduces these to six or seven very general questions. EPA-HQ-OPPT-2016-0426-0070 p.25 (JA:___) (codified at 40 C.F.R. § 710.37(c)). EPA no longer asks, *inter alia*, whether the information is readily discoverable, whether it has been patented, whether it has been licensed, whether competitors already know it, whether the confidentiality claim might go stale over time, or whether it is a trade secret. *Compare* EPA-HQ-OPPT-2016-0426-0001 p.14 (JA:___), *with* EPA-HQ-OPPT-2016-0426-0070 p.25 (JA:__-___). If the public had known EPA would not be seeking any of this information, the public could

have provided comments explaining why this information is crucial to establishing whether a confidentiality claim is sound. But since EPA proposed that it *would* seek this information, the public had no opportunity to comment on the need to do so.

In addition, both EDF and one industry commenter alerted EPA to the failure of the proposed rule to address the § 14 requirements clearly. EPA-HQ-OPPT-2016-0426-0064 p.17 (JA:___); EPA-HQ-OPPT-2016-0426-0039 p.3 (JA:___). EPA failed to respond to these comments.

### C. The final rule fails to incorporate the procedural requirements of TSCA § 14.

The final rule states that confidentiality claims will be "treated and disclosed in accordance with 40 CFR part 2, subpart B." EPA-HQ-OPPT-2016-0426-0070 p.24 (JA:___) (40 C.F.R. § 710.37(b)). But the subpart B regulations preceded and hence do not include the procedural requirements of Lautenberg, so following only them is contrary to law. 40 C.F.R. §§ 2.201-2.311.

*First*, TSCA imposes a proactive, affirmative duty for EPA to review certain confidentiality claims within a 90-day window, but the regulations do not incorporate that duty and it does not appear in subpart B. EPA's subpart B regulations only require EPA to review confidentiality claims in certain specified circumstances, 40 C.F.R. § 2.204(a), and the subpart B regulations do not include deadlines for action. Neither does the Inventory rule. *See* EPA-HQ-OPPT-2016-

0426-0070 pp.24-25 (JA:___) (codified at 40 C.F.R. § 710.37). The result is that, under the text of the regulations as promulgated, EPA does not have to review confidentiality claims except as provided by § 2.204(a) and EPA does not have deadlines for action.

But under TSCA § 14, EPA has an obligation to review many claims within a 90-day window. 15 U.S.C. § 2613(g)(1)(A).[6] For example, TSCA § 14 generally requires that EPA must review all claims for confidentiality for specific chemical identity, and EPA must reach a final decision on those requests. *Id.* § 2613(g)(1)(C)(i). When a person submits a notice seeking to change the designation of a confidential chemical from "inactive" to "active," the person must assert and substantiate any confidentiality claim for the specific chemical identity, and EPA must review and decide such a claim within 90 days. *Id.* §§ 2607(b)(5)(B), 2613(g)(1). But the final rule does not include these requirements.

The problem extends to other claims for confidentiality as well. Under TSCA § 14, EPA "shall *** review a representative subset, comprising at least 25 percent, of all" other confidentiality claims (except for information described in

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[6] Of course, the 90-day window does not apply to the "existing claims" for specific chemical identity which are properly requested to be maintained in the Inventory process and subject to the five-year review plain. *See* 15 U.S.C. § 2607(b)(4)(E)(i).

TSCA § 14(c)(2)). *Id.* § 2613(g)(1)(C)(ii). EPA is supposed to complete that review "not later than 90 days after the receipt of a claim." *Id.* § 2613(g)(1)(A). Thus, EPA should review at least 25% of all of those non-chemical identity confidentiality claims that it receives through the Inventory Notification within 90 days of their receipt.

But the final rule does not include any obligation to review claims and it also fails to provide any deadlines. *See* EPA-HQ-OPPT-2016-0426-0070 pp.24-25 (JA:___-___). And if EPA proceeds under the rule and treats the information "in accordance with 40 CFR part 2, subpart B," then EPA would not have an obligation to review these claims.

*Second*, under TSCA § 14, if EPA denies a claim of confidentiality at the end of the 90-day window, EPA must inform the claimant. 15 U.S.C. § 2613(g)(2). The claimant then has 30 days to seek an appeal by bringing an action in district court. *Id.* § 2613(g)(2)(D). In contrast, the subpart B regulations provide an administrative comment and appeal process. 40 C.F.R. §§ 2.204, 2.205. EPA has not reconciled how this process interacts with EPA's obligation to determine claims within the 90-day window or with Congress' decision to have appeals proceed directly to the district court.

*Third*, under TSCA § 26(j)(1), "[s]ubject to section 14, [EPA] shall make available to the public—all notices, determinations, findings, rules, consent

agreements, and orders of [EPA] under this title." 15 U.S.C. § 2625(j)(1). EPA's rulings on confidentiality claims are described as "determination[s]" in TSCA § 14, and even if they were not determinations, they would be findings or orders. *Id.* § 2613(g)(1). Thus, EPA has an affirmative obligation to make these determinations public, but EPA has not incorporated that requirement into its confidentiality regulations and it also does not appear in the subpart B regulations.

To be sure, in the preamble, EPA acknowledges one of these obligations under TSCA § 14: EPA's obligation to review certain claims (though EPA does not acknowledge its deadlines). *See* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:___). But EPA failed to include any text in the rule to execute those obligations, and by relying on the subpart B regulations, EPA created a regulatory scheme that will result in noncompliance with TSCA § 14.

## IV. The final rule fails to implement the unique identifier and other public information requirements in TSCA § 8(b)(7)(B).

The final rule fails to implement the "unique identifier" and other "public information" requirements for chemicals with confidential chemical identities. TSCA § 8(b)(7) expressly states that: "[EPA] shall make available to the public *** the unique identifier assigned under section 14, accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the [Inventory] for which a claim of confidentiality was received." 15 U.S.C. § 2607(b)(7). Thus, when EPA identifies

an active chemical on the Inventory as "confidential," EPA must provide a "unique identifier" for that chemical. *Id.*

TSCA § 14 explains that EPA must "apply [the unique] identifier consistently to all information relevant to the applicable chemical substance." *Id.* § 2613(g)(4)(A)(ii). Unique identifiers would ensure that, during the period when the chemical identity is protected from disclosure, various pieces of information associated with the chemical that EPA receives or develops that are not confidential, and therefore are made public, are linked by the same unique identifier so that the public can understand what information is available on such a chemical and that all such information applies to the same chemical.

TSCA § 8(b)(7) requires that those unique identifiers be made public. *Id.* § 2607(b)(7). In its comment, EDF explained to EPA that it needed to integrate this requirement into the Inventory Rule. "EPA is required to make public unique identifiers and other identifying information on chemicals that have not traditionally been included on the Inventory." EPA-HQ-OPPT-2016-0426-0002 p.7 (JA:___).

EPA completely failed to implement the unique identifier requirement of TSCA § 8(b)(7). Notably, EPA acknowledged that "TSCA section 8(b)(7) requires EPA to make active and inactive designations available to the public," and EPA recognized that it would do so "as soon as practicable after the close of the

retrospective submission period." EPA-HQ-OPPT-2016-0426-0086 p.27 (JA:___). Thus, EPA apparently understood that it had to implement the requirements of TSCA § 8(b)(7) when updating the Inventory under this rule. But EPA gave no indication whether it would—and if not, no explanation for why it would not—also implement the unique identifier requirement of TSCA § 8(b)(7).

Indeed, EPA provided no response to EDF's comment on the unique identifier issue, even though it acknowledged our broader comment pertaining to § 8(b)(7). EPA-HQ-OPPT-2016-0426-0086 p.57 (JA:___). The word "unique" does not even appear in the rule, preamble, or response to comments. EPA's failure to implement this aspect of TSCA § 8(b)(7) is contrary to law. EPA's analysis is also arbitrary and capricious because EPA "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. In addition, EPA failed to respond to a major substantive comment, and this Court "will often find agency decisions arbitrary or capricious where the agency has failed to respond to major substantive comments." *Sierra Club v. EPA*, 863 F.3d 834, 838 (D.C. Cir. 2017). EDF's comment that EPA needed to implement one of the statutory requirements for the Inventory when updating the Inventory merited some response.

## V. The final rule exempts chemicals manufactured and processed solely for export from the reporting requirements, even though such chemicals are specifically not exempted from § 8.

TSCA § 8(b)(4)(A)(i) directs that EPA "shall require manufacturers *** to notify [EPA] *** of each chemical substance on the [Inventory] that the manufacturer *** has manufactured *** for a *nonexempt* commercial purpose during the 10-year" look-back period. 15 U.S.C. § 2607(b)(4)(A)(i) (emphasis added). In the final rule, EPA illegally treated manufacture or processing solely for export as exempt when Congress expressly has decided that the exemption for export-only chemicals does *not* apply to reporting under TSCA § 8. 15 U.S.C. § 2611(a)(1).

In the proposed rule, EPA adopted a plausible interpretation of "nonexempt" based on the "commonly-accepted usage at the time that TSCA was amended, in 2016." EPA-HQ-OPPT-2016-0426-0001 p.5 (JA:___). EPA implemented this interpretation by defining certain "[a]ctivities for which notification is not required." EPA-HQ-OPPT-2016-0426-0001 at p.12 (JA:___) (to be codified at 40 C.F.R. § 710.27). Based on this approach, under the proposed rule manufacturers still had to notify EPA of export-only chemicals and such chemicals would have been listed as "active" on the Inventory.

In the final rule, EPA decided that manufacturers and processors did not have to report "[t]he manufacturing or processing of a chemical substance solely

for export from the United States as described in [40 C.F.R.] § 720.30(e) or § 721.3." EPA-HQ-OPPT-2016-0426-0070 p.22 (JA:___) (40 C.F.R. § 710.27(a)(4)). EPA acknowledged that "TSCA section 12(a)(1) authorizes EPA to include substances manufactured or processed solely for export in TSCA section 8 reporting," but EPA then found such manufacturing or processing to be exempt. EPA-HQ-OPPT-2016-0426-0070 p.9 (JA:___).

The actual language of TSCA § 12 forecloses EPA's new approach. TSCA § 12(a)(1) states that "[e]xcept as provided in paragraph (2) and subsections (b) and (c), this Act (*other than section 8*) shall not apply to any chemical substance" if it is manufactured or processed solely for export and meets certain requirements. 15 U.S.C. § 2611(a)(1) (emphasis added). Thus, the exemption provided by TSCA § 12 expressly does *not* exempt export-only chemicals from TSCA § 8, and it is TSCA § 8 that includes the Inventory provisions at issue here. *See id.* § 2607(b)(4). Congress expressly decided that section 8 *shall* apply to such chemicals. For purposes of § 8, chemicals manufactured or processed solely for export are "nonexempt." EPA completely failed to grapple with this statutory text.

"[I]t is a commonplace of statutory construction that the specific governs the general." *RadLAX Gateway Hotel, LLC v. Amalgamated Bank*, 566 U.S. 639, 645 (2012) (quoting *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 384 (1992)); *HCSC-Laundry v. United States*, 450 U.S. 1, 6 (1981) (the specific governs the

general "particularly when the two are interrelated and closely positioned"). "The general/specific canon is perhaps most frequently applied to statutes in which a general permission or prohibition is contradicted by a specific prohibition or permission. To eliminate the contradiction, the specific provision is construed as an exception to the general one." *RadLAX*, 566 U.S. at 645. Here, Congress exempted export-only chemicals from most of TSCA but specifically noted that TSCA § 8 continued to apply to such chemicals. EPA's conclusion that the exemption also applies to reporting under TSCA § 8 contradicts Congress's choice.

In addition, the proposed rule never suggested that EPA might exempt reporting for export-only chemicals, and indeed, the word "export" did not appear in the proposed rule or its preamble. As a result, the public had no opportunity to comment on this exemption.

## VI. EDF requests partial vacatur and a remand.

For the above reasons, EDF respectfully requests that this Court grant the petition for review and "set[] aside" this rule in part. 15 U.S.C. § 2618(c)(2). Vacatur, along with remand, is the presumptively appropriate remedy for a violation of the APA. *Am. Bioscience, Inc. v. Thompson*, 269 F.3d 1077, 1084 (D.C. Cir. 2001). But here a complete vacatur would postpone the release of some of the very information that EDF seeks, since it would allow EPA to postpone publishing the Inventory based on the information it has already collected. In

addition, it would impose costs on the regulated community beyond those necessary to remedy EDF's harms. Those manufacturers and processors who have already filed notices without claims of confidentiality should not need to refile the notices.

Here, EDF respectfully requests that the Court vacate the following provisions of the rule: 40 C.F.R. §§ 710.27(a)(4) (exclusion for export-only manufacturers), 710.37 (Confidentiality Claims), as well as the following portions of the preamble: II.A.2.ii, II.E.

EDF also respectfully requests that the Court remand to EPA with instructions that it promulgate a regulation consistent with the Court's opinion within six months of the Court's decision. Specifically, the Court should order EPA to promulgate a regulation that:

1) Requires any manufacturer or processor that filed a notice to maintain an existing claim for confidentiality for the specific chemical identity of an active chemical to withdraw that claim unless they (or their predecessor-in-interest) had asserted a confidentiality claim for that specific chemical identity before June 22, 2016.
2) Require that EPA review confidentiality claims under the procedural and substantive requirements of TSCA §§ 8 and 14, including a requirement that persons substantiate claims as required by TSCA §§ 8 and 14.

3) Implement the public information requirements of TSCA § 8(b)(7)(B) by listing the unique identifier assigned under section 14, accession number, generic name, and, if applicable, premanufacture notice case number for each chemical on the confidential portion of the Inventory.

4) Require that manufacturers or processors notify EPA of any activities during the lookback period that were excluded as manufacturing or processing for export only under 40 C.F.R. § 710.27(a)(4).

## CONCLUSION

For the above reasons, EDF requests that the Court grant the petition for review.

Respectfully submitted,

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# STATUTORY ADDENDUM

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mixture, or that any combination of such activities, is likely to result in such injury to health or the environment before a final rule under section 2605 of this title can protect against such risk.

(Pub. L. 94–469, title I, § 7, Oct. 11, 1976, 90 Stat. 2026; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 102–550, title X, § 1021(b)(1), Oct. 28, 1992, 106 Stat. 3923; Pub. L. 114–182, title I, §§ 7, 19(f), June 22, 2016, 130 Stat. 470, 507.)

AMENDMENTS

2016—Subsec. (a)(1). Pub. L. 114–182, § 19(f)(1), in concluding provisions, substituted ''a determination under section 2604 or 2605 of this title, a rule under section 2603, 2604, or 2605 of this title or subchapter IV, an order under section 2603, 2604, or 2605 of this title or subchapter IV, or a consent agreement under section 2603 of this title'' for ''a rule under section 2603 of this title, 2604 of this title, 2605 of this title, or subchapter IV or an order under section 2604 of this title or subchapter IV''.

Subsec. (a)(2). Pub. L. 114–182, § 19(f)(2), substituted ''section 2605(d)(3)(A)(i)'' for ''section 2605(d)(2)(A)(i)''.

Subsec. (b)(1). Pub. L. 114–182, § 7(1), inserted ''(as identified by the Administrator without consideration of costs or other nonrisk factors)'' after ''from the unreasonable risk''.

Subsec. (f). Pub. L. 114–182, § 7(2), inserted '', without consideration of costs or other nonrisk factors'' after ''widespread injury to health or the environment''.

1992—Subsec. (a)(1). Pub. L. 102–550 substituted ''section 2603 of this title, 2604 of this title, 2605 of this title, or subchapter IV'' for ''section 2603, 2604, or 2605 of this title'' in last sentence.

Pub. L. 102–550, which directed the insertion of ''or subchapter IV'' after ''2604'', was executed by making the insertion after ''2604'' the second time appearing in last sentence, to reflect the probable intent of Congress.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

### § 2607. Reporting and retention of information

#### (a) Reports

(1) The Administrator shall promulgate rules under which—

(A) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process a chemical substance (other than a chemical substance described in subparagraph (B)(ii)) shall maintain such records, and shall submit to the Administrator such reports, as the Administrator may reasonably require, and

(B) each person (other than a small manufacturer or processor) who manufactures or processes or proposes to manufacture or process—

(i) a mixture, or

(ii) a chemical substance in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including any such research or analysis for the development of a product,

shall maintain records and submit to the Administrator reports but only to the extent the Administrator determines the maintenance of records or submission of reports, or both, is necessary for the effective enforcement of this chapter.

The Administrator may not require in a rule promulgated under this paragraph the maintenance of records or the submission of reports with respect to changes in the proportions of the components of a mixture unless the Administrator finds that the maintenance of such records or the submission of such reports, or both, is necessary for the effective enforcement of this chapter. For purposes of the compilation of the list of chemical substances required under subsection (b), the Administrator shall promulgate rules pursuant to this subsection not later than 180 days after January 1, 1977.

(2) The Administrator may require under paragraph (1) maintenance of records and reporting with respect to the following insofar as known to the person making the report or insofar as reasonably ascertainable:

(A) The common or trade name, the chemical identity, and the molecular structure of each chemical substance or mixture for which such a report is required.

(B) The categories or proposed categories of use of each such substance or mixture.

(C) The total amount of each such substance and mixture manufactured or processed, reasonable estimates of the total amount to be manufactured or processed, the amount manufactured or processed for each of its categories of use, and reasonable estimates of the amount to be manufactured or processed for each of its categories of use or proposed categories of use.

(D) A description of the byproducts resulting from the manufacture, processing, use, or disposal of each such substance or mixture.

(E) All existing information concerning the environmental and health effects of such substance or mixture.

(F) The number of individuals exposed, and reasonable estimates of the number who will be exposed, to such substance or mixture in their places of employment and the duration of such exposure.

(G) In the initial report under paragraph (1) on such substance or mixture, the manner or method of its disposal, and in any subsequent report on such substance or mixture, any change in such manner or method.

(3)(A)(i) The Administrator may by rule require a small manufacturer or processor of a chemical substance to submit to the Administrator such information respecting the chemical substance as the Administrator may require for publication of the first list of chemical substances required by subsection (b).

(ii) The Administrator may by rule require a small manufacturer or processor of a chemical substance or mixture—

(I) subject to a rule proposed or promulgated under section 2603, 2604(b)(4), or 2605 of this title,,[1] an order in effect under section 2603 or 2604(e) of this title, or a consent agreement under section 2603 of this title, or

[1] So in original.

(II) with respect to which relief has been granted pursuant to a civil action brought under section 2604 or 2606 of this title,

to maintain such records on such substance or mixture, and to submit to the Administrator such reports on such substance or mixture, as the Administrator may reasonably require. A rule under this clause requiring reporting may require reporting with respect to the matters referred to in paragraph (2).

(B) The Administrator, after consultation with the Administrator of the Small Business Administration, shall by rule prescribe standards for determining the manufacturers and processors which qualify as small manufacturers and processors for purposes of this paragraph and paragraph (1).

(C) Not later than 180 days after June 22, 2016, and not less frequently than once every 10 years thereafter, the Administrator, after consultation with the Administrator of the Small Business Administration, shall—

(i) review the adequacy of the standards prescribed under subparagraph (B); and

(ii) after providing public notice and an opportunity for comment, make a determination as to whether revision of the standards is warranted.

(4) CONTENTS.—The rules promulgated pursuant to paragraph (1)—

(A) may impose differing reporting and recordkeeping requirements on manufacturers and processors; and

(B) shall include the level of detail necessary to be reported, including the manner by which use and exposure information may be reported.

(5) ADMINISTRATION.—In carrying out this section, the Administrator shall, to the extent feasible—

(A) not require reporting which is unnecessary or duplicative;

(B) minimize the cost of compliance with this section and the rules issued thereunder on small manufacturers and processors; and

(C) apply any reporting obligations to those persons likely to have information relevant to the effective implementation of this subchapter.

(6) NEGOTIATED RULEMAKING.—(A) The Administrator shall enter into a negotiated rulemaking pursuant to subchapter III of chapter 5 of title 5 to develop and publish, not later than 3 years after June 22, 2016, a proposed rule providing for limiting the reporting requirements, under this subsection, for manufacturers of any inorganic byproducts, when such byproducts, whether by the byproduct manufacturer or by any other person, are subsequently recycled, reused, or reprocessed.

(B) Not later than 3 and one-half years after June 22, 2016, the Administrator shall publish a final rule resulting from such negotiated rulemaking.

**(b) Inventory**

(1) The Administrator shall compile, keep current, and publish a list of each chemical substance which is manufactured or processed in the United States. Such list shall at least include each chemical substance which any person reports, under section 2604 of this title or subsection (a) of this section, is manufactured or processed in the United States. Such list may not include any chemical substance which was not manufactured or processed in the United States within three years before the effective date of the rules promulgated pursuant to the last sentence of subsection (a)(1). In the case of a chemical substance for which a notice is submitted in accordance with section 2604 of this title, such chemical substance shall be included in such list as of the earliest date (as determined by the Administrator) on which such substance was manufactured or processed in the United States. The Administrator shall first publish such a list not later than 315 days after January 1, 1977. The Administrator shall not include in such list any chemical substance which is manufactured or processed only in small quantities (as defined by the Administrator by rule) solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product.

(2) To the extent consistent with the purposes of this chapter, the Administrator may, in lieu of listing, pursuant to paragraph (1), a chemical substance individually, list a category of chemical substances in which such substance is included.

(3) NOMENCLATURE.—

(A) IN GENERAL.—In carrying out paragraph (1), the Administrator shall—

(i) maintain the use of Class 2 nomenclature in use on June 22, 2016;

(ii) maintain the use of the Soap and Detergent Association Nomenclature System, published in March 1978 by the Administrator in section 1 of addendum III of the document entitled ''Candidate List of Chemical Substances'', and further described in the appendix A of volume I of the 1985 edition of the Toxic Substances Control Act Substances Inventory (EPA Document No. EPA–560/7–85–002a); and

(iii) treat the individual members of the categories of chemical substances identified by the Administrator as statutory mixtures, as defined in Inventory descriptions established by the Administrator, as being included on the list established under paragraph (1).

(B) MULTIPLE NOMENCLATURE LISTINGS.—If a manufacturer or processor demonstrates to the Administrator that a chemical substance appears multiple times on the list published under paragraph (1) under different CAS numbers, the Administrator may recognize the multiple listings as a single chemical substance.

(4) CHEMICAL SUBSTANCES IN COMMERCE.—

(A) RULES.—

(i) IN GENERAL.—Not later than 1 year after June 22, 2016, the Administrator, by rule, shall require manufacturers, and may require processors, subject to the limitations under subsection (a)(5)(A), to notify the Administrator, by not later than 180 days after

the date on which the final rule is published in the Federal Register, of each chemical substance on the list published under paragraph (1) that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before June 22, 2016.

(ii) ACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which notices are received under clause (i) to be active substances on the list published under paragraph (1).

(iii) INACTIVE SUBSTANCES.—The Administrator shall designate chemical substances for which no notices are received under clause (i) to be inactive substances on the list published under paragraph (1).

(iv) LIMITATION.—No chemical substance on the list published under paragraph (1) shall be removed from such list by reason of the implementation of this subparagraph, or be subject to section 2604(a)(1)(A)(i) of this title by reason of a change to active status under paragraph (5)(B).

(B) CONFIDENTIAL CHEMICAL SUBSTANCES.—In promulgating a rule under subparagraph (A), the Administrator shall—

(i) maintain the list under paragraph (1), 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.

(C) REVIEW PLAN.—Not later than 1 year after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A), the Administrator shall promulgate a rule that establishes a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the list published under paragraph (1) that are asserted pursuant to subparagraph (B).

(D) REQUIREMENTS OF REVIEW PLAN.—In establishing the review plan under subparagraph (C), the Administrator shall—

(i) require, at a time specified by the Administrator, all manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim, in accordance with section 2613 of this title, unless the manufacturer or processor has substantiated the claim in a submission made to the Administrator during the 5-year period ending on the last day of the of the time period specified by the Administrator; and

(ii) in accordance with section 2613 of this title—

(I) review each substantiation—

(aa) submitted pursuant to clause (i) to determine if the claim qualifies for protection from disclosure; and

(bb) submitted previously by a manufacturer or processor and relied on in lieu of the substantiation required pursuant to clause (i), if the substantiation has not been previously reviewed by the Administrator, to determine if the claim warrants protection from disclosure;

(II) approve, approve in part and deny in part, or deny each claim; and

(III) except as provided in this section and section 2613 of this title, protect from disclosure information for which the Administrator approves such a claim for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall not protect the information from disclosure; or

(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 2613(g)(2) of this title.

(E) TIMELINE FOR COMPLETION OF REVIEWS.—

(i) IN GENERAL.—The Administrator shall implement the review plan so as to complete reviews of all claims specified in subparagraph (C) not later than 5 years after the date on which the Administrator compiles the initial list of active substances pursuant to subparagraph (A).

(ii) CONSIDERATIONS.—

(I) IN GENERAL.—The Administrator may extend the deadline for completion of the reviews for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of claims needing review and the available resources.

(II) ANNUAL REVIEW GOAL AND RESULTS.—At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year.

(5) ACTIVE AND INACTIVE SUBSTANCES.—

(A) IN GENERAL.—The Administrator shall keep designations of active substances and inactive substances on the list published under paragraph (1) current.

(B) CHANGE TO ACTIVE STATUS.—

(i) IN GENERAL.—Any person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance

that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed.

(ii) CONFIDENTIAL CHEMICAL IDENTITY.—If a person submitting a notice under clause (i) for an inactive substance on the confidential portion of the list published under paragraph (1) seeks to maintain an existing claim for protection against disclosure of the specific chemical identity of the inactive substance as confidential, the person shall, consistent with the requirements of section 2613 of this title—

(I) in the notice submitted under clause (i), assert the claim; and

(II) by not later than 30 days after providing the notice under clause (i), substantiate the claim.

(iii) ACTIVE STATUS.—On receiving a notification under clause (i), the Administrator shall—

(I) designate the applicable chemical substance as an active substance;

(II) pursuant to section 2613 of this title, promptly review any claim and associated substantiation submitted pursuant to clause (ii) for protection against disclosure of the specific chemical identity of the chemical substance and approve, approve in part and deny in part, or deny the claim;

(III) except as provided in this section and section 2613 of this title, protect from disclosure the specific chemical identity of the chemical substance for which the Administrator approves a claim under subclause (II) for a period of 10 years, unless, prior to the expiration of the period—

(aa) the person notifies the Administrator that the person is withdrawing the claim, in which case the Administrator shall not protect the information from disclosure; or

(bb) the Administrator otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Administrator shall take the actions described in section 2613(g)(2) of this title; and

(IV) pursuant to section 2605(b) of this title, review the priority of the chemical substance as the Administrator determines to be necessary.

(C) CATEGORY STATUS.—The list of inactive substances shall not be considered to be a category for purposes of section 2625(c) of this title.

(6) INTERIM LIST OF ACTIVE SUBSTANCES.—Prior to the promulgation of the rule required under paragraph (4)(A), the Administrator shall designate the chemical substances reported under part 711 of title 40, Code of Federal Regulations (as in effect on June 22, 2016), during the reporting period that most closely preceded June 22, 2016, as the interim list of active substances for the purposes of section 2605(b) of this title.

(7) PUBLIC INFORMATION.—Subject to this subsection and section 2613 of this title, the Administrator shall make available to the public—

(A) each specific chemical identity on the nonconfidential portion of the list published under paragraph (1) along with the Administrator's designation of the chemical substance as an active or inactive substance;

(B) the unique identifier assigned under section 2613 of this title, accession number, generic name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the list published under paragraph (1) for which a claim of confidentiality was received; and

(C) the specific chemical identity of any active substance for which—

(i) a claim for protection against disclosure of the specific chemical identity of the active substance was not asserted, as required under this subsection or section 2613 of this title;

(ii) all claims for protection against disclosure of the specific chemical identity of the active substance have been denied by the Administrator; or

(iii) the time period for protection against disclosure of the specific chemical identity of the active substance has expired.

(8) LIMITATION.—No person may assert a new claim under this subsection or section 2613 of this title 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) that is not on the confidential portion of the list published under paragraph (1).

(9) CERTIFICATION.—Under the rules promulgated under this subsection, manufacturers and processors, as applicable, shall be required—

(A) to certify that each notice or substantiation the manufacturer or processor submits complies with the requirements of the rule, and that any confidentiality claims are true and correct; and

(B) to retain a record documenting compliance with the rule and supporting confidentiality claims for a period of 5 years beginning on the last day of the submission period.

(10) MERCURY.—

(A) DEFINITION OF MERCURY.—In this paragraph, notwithstanding section 2602(2)(B) of this title, the term ''mercury'' means—

(i) elemental mercury; and

(ii) a mercury compound.

(B) PUBLICATION.—Not later than April 1, 2017, and every 3 years thereafter, the Administrator shall carry out and publish in the Federal Register an inventory of mercury supply, use, and trade in the United States.

(C) PROCESS.—In carrying out the inventory under subparagraph (B), the Administrator shall—

(i) identify any manufacturing processes or products that intentionally add mercury; and

(ii) recommend actions, including proposed revisions of Federal law or regulations, to achieve further reductions in mercury use.

(D) REPORTING.—

(i) IN GENERAL.—To assist in the preparation of the inventory under subparagraph

(B), any person who manufactures mercury or mercury-added products or otherwise intentionally uses mercury in a manufacturing process shall make periodic reports to the Administrator, at such time and including such information as the Administrator shall determine by rule promulgated not later than 2 years after June 22, 2016.

(ii) COORDINATION.—To avoid duplication, the Administrator shall coordinate the reporting under this subparagraph with the Interstate Mercury Education and Reduction Clearinghouse.

(iii) EXEMPTION.—Clause (i) shall not apply to a person engaged in the generation, handling, or management of mercury-containing waste, unless that person manufactures or recovers mercury in the management of that waste.

**(c) Records**

Any person who manufactures, processes, or distributes in commerce any chemical substance or mixture shall maintain records of significant adverse reactions to health or the environment, as determined by the Administrator by rule, alleged to have been caused by the substance or mixture. Records of such adverse reactions to the health of employees shall be retained for a period of 30 years from the date such reactions were first reported to or known by the person maintaining such records. Any other record of such adverse reactions shall be retained for a period of five years from the date the information contained in the record was first reported to or known by the person maintaining the record. Records required to be maintained under this subsection shall include records of consumer allegations of personal injury or harm to health, reports of occupational disease or injury, and reports or complaints of injury to the environment submitted to the manufacturer, processor, or distributor in commerce from any source. Upon request of any duly designated representative of the Administrator, each person who is required to maintain records under this subsection shall permit the inspection of such records and shall submit copies of such records.

**(d) Health and safety studies**

The Administrator shall promulgate rules under which the Administrator shall require any person who manufactures, processes, or distributes in commerce or who proposes to manufacture, process, or distribute in commerce any chemical substance or mixture (or with respect to paragraph (2), any person who has possession of a study) to submit to the Administrator—

(1) lists of health and safety studies (A) conducted or initiated by or for such person with respect to such substance or mixture at any time, (B) known to such person, or (C) reasonably ascertainable by such person, except that the Administrator may exclude certain types or categories of studies from the requirements of this subsection if the Administrator finds that submission of lists of such studies are unnecessary to carry out the purposes of this chapter; and

(2) copies of any study contained on a list submitted pursuant to paragraph (1) or otherwise known by such person.

**(e) Notice to Administrator of substantial risks**

Any person who manufactures, processes, or distributes in commerce a chemical substance or mixture and who obtains information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment shall immediately inform the Administrator of such information unless such person has actual knowledge that the Administrator has been adequately informed of such information.

**(f) "Manufacture" and "process" defined**

For purposes of this section, the terms ''manufacture'' and ''process'' mean manufacture or process for commercial purposes.

(Pub. L. 94–469, title I, § 8, Oct. 11, 1976, 90 Stat. 2027; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114–182, title I, §§ 8, 19(g), June 22, 2016, 130 Stat. 470, 507.)

AMENDMENTS

2016—Subsec. (a)(2). Pub. L. 114–182, § 8(a)(1)(A), struck out concluding provisions which read as follows: ''To the extent feasible, the Administrator shall not require under paragraph (1), any reporting which is unnecessary or duplicative.''

Subsec. (a)(2)(E). Pub. L. 114–182, § 19(g)(1), substituted ''information'' for ''data''.

Subsec. (a)(3)(A)(ii)(I). Pub. L. 114–182, § 19(g)(2), substituted '', an order in effect under section 2603 or 2604(e) of this title, or a consent agreement under section 2603 of this title'' for ''or an order in effect under section 2604(e) of this title''.

Subsec. (a)(3)(C). Pub. L. 114–182, § 8(a)(1)(B), added subpar. (C).

Subsec. (a)(4) to (6). Pub. L. 114–182, § 8(a)(1)(C), added pars. (4) to (6).

Subsec. (b)(3) to (9). Pub. L. 114–182, § 8(a)(2), added pars. (3) to (9).

Subsec. (b)(10). Pub. L. 114–182, § 8(b), added par. (10).

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

ASBESTOS INFORMATION

Pub. L. 100–577, Oct. 31, 1988, 102 Stat. 2901, provided that:

''SECTION 1. SHORT TITLE.

''This Act may be cited as the 'Asbestos Information Act of 1988'.

''SEC. 2. SUBMISSION OF INFORMATION BY MANUFACTURERS.

''Within 90 days after the date of the enactment of this Act [Oct. 31, 1988], any person who manufactured or processed, before the date of the enactment of this Act, asbestos or asbestos-containing material that was prepared for sale for use as surfacing material, thermal system insulation, or miscellaneous material in buildings (or whose corporate predecessor manufactured or processed such asbestos or material) shall submit to the Administrator of the Environmental Protection Agency the years of manufacture, the types or classes of product, and, to the extent available, other identifying characteristics reasonably necessary to identify or distinguish the asbestos or asbestos-containing material. Such person also may submit to the Administrator protocols for samples of asbestos and asbestos-containing material.

''SEC. 3. PUBLICATION OF INFORMATION.

''Within 30 days after the date of the enactment of this Act [Oct. 31, 1988], the Administrator shall publish

a notice in the Federal Register that explains how, when, and where the information specified in section 2 is to be submitted. The Administrator shall receive and organize the information submitted under section 2 and, within 180 days after the date of the enactment of this Act, shall publish the information. In carrying out this section, the Administrator may not—

''(1) review the information submitted under section 2 for accuracy, or

''(2) analyze such information to determine whether it is reasonably necessary to identify or distinguish the particular asbestos or asbestos-containing material.

''SEC. 4. DEFINITIONS.

''In this Act:

''(1) The term 'asbestos' means—

''(A) chrysotile, amosite, or crocidolite, or

''(B) in fibrous form, tremolite, anthophyllite, or actinolite.

''(2) The term 'asbestos-containing material' means any material containing more than one percent asbestos by weight.

''(3) The term 'identifying characteristics' means a description of asbestos or asbestos-containing material, including—

''(A) the mineral or chemical constituents (or both) of the asbestos or material by weight or volume (or both),

''(B) the types or classes of the product in which the asbestos or material is contained,

''(C) the designs, patterns, or textures of the product in which the asbestos or material is contained, and

''(D) the means by which the product in which the asbestos or material is contained may be distinguishable from other products containing asbestos or asbestos-containing material.

''(4) The term 'miscellaneous material' means building material on structural components, structural members, or fixtures, such as floor and ceiling tiles. The term does not include surfacing material or thermal system insulation.

''(5) The term 'protocol' means any procedure for taking, handling, and preserving samples of asbestos and asbestos-containing material and for testing and analyzing such samples for the purpose of determining the person who manufactured or processed for sale such samples and the identifying characteristics of such samples.

''(6) The term 'surfacing material' means material in a building that is sprayed on surfaces, troweled on surfaces, or otherwise applied to surfaces for acoustical, fireproofing, or other purposes, such as acoustical plaster on ceilings and fireproofing material on structural members.

''(7) The term 'thermal system insulation' means material in a building applied to pipes, fittings, boilers, breeching, tanks, ducts, or other structural components to prevent heat loss or gain or water condensation, or for other purposes.''

### § 2608. Relationship to other Federal laws

#### (a) Laws not administered by the Administrator

(1) If the Administrator determines that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture, or that any combination of such activities, 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, and determines, in the Administrator's discretion, that such risk may be prevented or reduced to a sufficient extent by action taken under a Federal law not administered by the Administrator, the Administrator shall submit to the agency which administers such law a report which describes such risk and includes in such description a specification of the activity or combination of activities which the Administrator has reason to believe so presents such risk. Such report shall also request such agency—

(A)(i) to determine if the risk described in such report may be prevented or reduced to a sufficient extent by action taken under such law, and

(ii) if the agency determines that such risk may be so prevented or reduced, to issue an order declaring whether or not the activity or combination of activities specified in the description of such risk presents such risk; and

(B) to respond to the Administrator with respect to the matters described in subparagraph (A).

Any report of the Administrator shall include a detailed statement of the information on which it is based and shall be published in the Federal Register. The agency receiving a request under such a report shall make the requested determination, issue the requested order, and make the requested response within such time as the Administrator specifies in the request, but such time specified may not be less than 90 days from the date the request was made. The response of an agency shall be accompanied by a detailed statement of the findings and conclusions of the agency and shall be published in the Federal Register.

(2) If the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which such report was made either—

(A) issues an order, within the time period specified by the Administrator in the report, declaring that the activity or combination of activities specified in the description of the risk described in the report does not present the risk described in the report, or

(B) responds within the time period specified by the Administrator in the report and initiates, within 90 days of the publication in the Federal Register of the response of the agency under paragraph (1), action under the law (or laws) administered by such agency to protect against such risk associated with such activity or combination of activities,

the Administrator may not take any action under section 2605(a) or 2606 of this title with respect to such risk.

(3) The Administrator shall take the actions described in paragraph (4) if the Administrator makes a report under paragraph (1) with respect to a chemical substance or mixture and the agency to which the report was made does not—

(A) issue the order described in paragraph (2)(A) within the time period specified by the Administrator in the report; or

(B)(i) respond under paragraph (1) within the timeframe specified by the Administrator in the report; and

(ii) initiate action within 90 days of publication in the Federal Register of the response described in clause (i).

training, demonstrations, and studies, beginning in fiscal year 2000 and thereafter, see provisions of title III of Pub. L. 106–74, set out as a note under section 136r of Title 7, Agriculture.

### § 2610. Inspections and subpoenas

#### (a) In general

For purposes of administering this chapter, the Administrator, and any duly designated representative of the Administrator, may inspect any establishment, facility, or other premises in which chemical substances, mixtures, or products subject to subchapter IV are manufactured, processed, stored, or held before or after their distribution in commerce and any conveyance being used to transport chemical substances, mixtures, such products, or such articles in connection with distribution in commerce. Such an inspection may only be made upon the presentation of appropriate credentials and of a written notice to the owner, operator, or agent in charge of the premises or conveyance to be inspected. A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness and shall be conducted at reasonable times, within reasonable limits, and in a reasonable manner.

#### (b) Scope

(1) Except as provided in paragraph (2), an inspection conducted under subsection (a) shall extend to all things within the premises or conveyance inspected (including records, files, papers, processes, controls, and facilities) bearing on whether the requirements of this chapter applicable to the chemical substances, mixtures, or products subject to subchapter IV within such premises or conveyance have been complied with.

(2) No inspection under subsection (a) shall extend to—

(A) financial information,

(B) sales information (other than shipment information),

(C) pricing information,

(D) personnel information, or

(E) research information (other than information required by this chapter or under a rule promulgated, order issued, or consent agreement entered into thereunder),

unless the nature and extent of such information are described with reasonable specificity in the written notice required by subsection (a) for such inspection.

#### (c) Subpoenas

In carrying out this chapter, the Administrator may by subpoena require the attendance and testimony of witnesses and the production of reports, papers, documents, answers to questions, and other information that the Administrator deems necessary. Witnesses shall be paid the same fees and mileage that are paid witnesses in the courts of the United States. In the event of contumacy, failure, or refusal of any person to obey any such subpoena, any district court of the United States in which venue is proper shall have jurisdiction to order any such person to comply with such subpoena. Any failure to obey such an order of the court is punishable by the court as a contempt thereof.

(Pub. L. 94–469, title I, § 11, Oct. 11, 1976, 90 Stat. 2032; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 102–550, title X, § 1021(b)(2), (3), Oct. 28, 1992, 106 Stat. 3923; Pub. L. 114–182, title I, § 19(j), June 22, 2016, 130 Stat. 507.)

AMENDMENTS

2016—Subsec. (b)(2). Pub. L. 114–182, § 19(j)(1), substituted ''information'' for ''data'' wherever appearing.

Subsec. (b)(2)(E). Pub. L. 114–182, § 19(j)(2), substituted ''rule promulgated, order issued, or consent agreement entered into'' for ''rule promulgated''.

1992—Subsec. (a). Pub. L. 102–550, § 1021(b)(2), in first sentence, substituted ''substances, mixtures, or products subject to subchapter IV'' for ''substances or mixtures'' and inserted ''such products,'' before ''or such articles''.

Subsec. (b)(1). Pub. L. 102–550, § 1021(b)(3), substituted ''chemical substances, mixtures, or products subject to subchapter IV'' for ''chemical substances or mixtures''.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

### § 2611. Exports

#### (a) In general

(1) Except as provided in paragraph (2) and subsections (b) and (c), this chapter (other than section 2607 of this title) shall not apply to any chemical substance, mixture, or to an article containing a chemical substance or mixture, if—

(A) it can be shown that such substance, mixture, or article is being manufactured, processed, or distributed in commerce for export from the United States, unless such substance, mixture, or article was, in fact, manufactured, processed, or distributed in commerce, for use in the United States, and

(B) such substance, mixture, or article (when distributed in commerce), or any container in which it is enclosed (when so distributed), bears a stamp or label stating that such substance, mixture, or article is intended for export.

(2) Paragraph (1) shall not apply to any chemical substance, mixture, or article if the Administrator finds that the substance, mixture, or article presents an unreasonable risk of injury to health within the United States or to the environment of the United States. The Administrator may require, under section 2603 of this title, testing of any chemical substance or mixture exempted from this chapter by paragraph (1) for the purpose of determining whether or not such substance or mixture presents an unreasonable risk of injury to health within the United States or to the environment of the United States.

#### (b) Notice

(1) If any person exports or intends to export to a foreign country a chemical substance or mixture for which the submission of information is required under section 2603 or 2604(b) of this title, such person shall notify the Administrator of such exportation or intent to export and the

Administrator shall furnish to the government of such country notice of the availability of the information submitted to the Administrator under such section for such substance or mixture.

(2) If any person exports or intends to export to a foreign country a chemical substance or mixture for which an order has been issued under section 2604 of this title or a rule has been proposed or promulgated under section 2604 or 2605 of this title, or with respect to which an action is pending, or relief has been granted under section 2604 or 2606 of this title, such person shall notify the Administrator of such exportation or intent to export and the Administrator shall furnish to the government of such country notice of such rule, order, action, or relief.

**(c) Prohibition on export of elemental mercury and mercury compounds**

**(1) Prohibition**

Effective January 1, 2013, the export of elemental mercury from the United States is prohibited.

**(2) Inapplicability of subsection (a)**

Subsection (a) shall not apply to this subsection.

**(3) Report to Congress on mercury compounds**

**(A) Report**

Not later than one year after October 14, 2008, the Administrator shall publish and submit to Congress a report on mercuric chloride, mercurous chloride or calomel, mercuric oxide, and other mercury compounds, if any, that may currently be used in significant quantities in products or processes. Such report shall include an analysis of—

(i) the sources and amounts of each of the mercury compounds imported into the United States or manufactured in the United States annually;

(ii) the purposes for which each of these compounds are used domestically, the amount of these compounds currently consumed annually for each purpose, and the estimated amounts to be consumed for each purpose in 2010 and beyond;

(iii) the sources and amounts of each mercury compound exported from the United States annually in each of the last three years;

(iv) the potential for these compounds to be processed into elemental mercury after export from the United States; and

(v) other relevant information that Congress should consider in determining whether to extend the export prohibition to include one or more of these mercury compounds.

**(B) Procedure**

For the purpose of preparing the report under this paragraph, the Administrator may utilize the information gathering authorities of this subchapter, including sections 2609 and 2610 of this title.

**(4) Essential use exemption**

(A) Any person residing in the United States may petition the Administrator for an exemption from the prohibition in paragraph (1), and the Administrator may grant by rule, after notice and opportunity for comment, an exemption for a specified use at an identified foreign facility if the Administrator finds that—

(i) nonmercury alternatives for the specified use are not available in the country where the facility is located;

(ii) there is no other source of elemental mercury available from domestic supplies (not including new mercury mines) in the country where the elemental mercury will be used;

(iii) the country where the elemental mercury will be used certifies its support for the exemption;

(iv) the export will be conducted in such a manner as to ensure the elemental mercury will be used at the identified facility as described in the petition, and not otherwise diverted for other uses for any reason;

(v) the elemental mercury will be used in a manner that will protect human health and the environment, taking into account local, regional, and global human health and environmental impacts;

(vi) the elemental mercury will be handled and managed in a manner that will protect human health and the environment, taking into account local, regional, and global human health and environmental impacts; and

(vii) the export of elemental mercury for the specified use is consistent with international obligations of the United States intended to reduce global mercury supply, use, and pollution.

(B) Each exemption issued by the Administrator pursuant to this paragraph shall contain such terms and conditions as are necessary to minimize the export of elemental mercury and ensure that the conditions for granting the exemption will be fully met, and shall contain such other terms and conditions as the Administrator may prescribe. No exemption granted pursuant to this paragraph shall exceed three years in duration and no such exemption shall exceed 10 metric tons of elemental mercury.

(C) The Administrator may by order suspend or cancel an exemption under this paragraph in the case of a violation described in subparagraph (D).

(D) A violation of this subsection or the terms and conditions of an exemption, or the submission of false information in connection therewith, shall be considered a prohibited act under section 2614 of this title, and shall be subject to penalties under section 2615 of this title, injunctive relief under section 2616 of this title, and citizen suits under section 2619 of this title.

**(5) Consistency with trade obligations**

Nothing in this subsection affects, replaces, or amends prior law relating to the need for consistency with international trade obligations.

**(6) Export of coal**

Nothing in this subsection shall be construed to prohibit the export of coal.

**(7) Prohibition on export of certain mercury compounds**

**(A) In general**

Effective January 1, 2020, the export of the following mercury compounds is prohibited:

(i) Mercury (I) chloride or calomel.

(ii) Mercury (II) oxide.

(iii) Mercury (II) sulfate.

(iv) Mercury (II) nitrate.

(v) Cinnabar or mercury sulphide.

(vi) Any mercury compound that the Administrator adds to the list published under subparagraph (B) by rule, on determining that exporting that mercury compound for the purpose of regenerating elemental mercury is technically feasible.

**(B) Publication**

Not later than 90 days after June 22, 2016, and as appropriate thereafter, the Administrator shall publish in the Federal Register a list of the mercury compounds that are prohibited from export under this paragraph.

**(C) Petition**

Any person may petition the Administrator to add a mercury compound to the list published under subparagraph (B).

**(D) Environmentally sound disposal**

This paragraph does not prohibit the export of mercury compounds on the list published under subparagraph (B) to member countries of the Organization for Economic Co-operation and Development for environmentally sound disposal, on the condition that no mercury or mercury compounds so exported are to be recovered, recycled, or reclaimed for use, or directly reused, after such export.

**(E) Report**

Not later than 5 years after June 22, 2016, the Administrator shall evaluate any exports of mercury compounds on the list published under subparagraph (B) for disposal that occurred after June 22, 2016, and shall submit to Congress a report that—

(i) describes volumes and sources of mercury compounds on the list published under subparagraph (B) exported for disposal;

(ii) identifies receiving countries of such exports;

(iii) describes methods of disposal used after such export;

(iv) identifies issues, if any, presented by the export of mercury compounds on the list published under subparagraph (B);

(v) includes an evaluation of management options in the United States for mercury compounds on the list published under subparagraph (B), if any, that are commercially available and comparable in cost and efficacy to methods being utilized in such receiving countries; and

(vi) makes a recommendation regarding whether Congress should further limit or prohibit the export of mercury compounds on the list published under subparagraph (B) for disposal.

**(F) Effect on other law**

Nothing in this paragraph shall be construed to affect the authority of the Administrator under the Solid Waste Disposal Act (42 U.S.C. 6901 et seq.).

(Pub. L. 94–469, title I, § 12, Oct. 11, 1976, 90 Stat. 2033; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 110–414, § 4, Oct. 14, 2008, 122 Stat. 4342; Pub. L. 114–182, title I, §§ 10(a), (b), 19(k), June 22, 2016, 130 Stat. 477, 508.)

REFERENCES IN TEXT

The Solid Waste Disposal Act, referred to in subsec. (c)(7)(F), is title II of Pub. L. 89–272, Oct. 20, 1965, 79 Stat. 997, as amended generally by Pub. L. 94–580, § 2, Oct. 21, 1976, 90 Stat. 2795, which is classified generally to chapter 82 (§ 6901 et seq.) of Title 42, The Public Health and Welfare. For complete classification of this Act to the Code, see Short Title note set out under section 6901 of Title 42 and Tables.

AMENDMENTS

2016—Subsec. (a)(2). Pub. L. 114–182, § 10(a), substituted ''presents'' for ''will present''.

Subsec. (b)(1). Pub. L. 114–182, § 19(k), substituted ''information'' for ''data'' in two places.

Subsec. (c). Pub. L. 114–182, § 10(b)(1), inserted ''and mercury compounds'' after ''mercury'' in heading.

Subsec. (c)(7). Pub. L. 114–182, § 10(b)(2), added par. (7).

2008—Subsec. (a)(1). Pub. L. 110–414, § 4(1), substituted ''subsections (b) and (c)'' for ''subsection (b)'' in introductory provisions.

Subsec. (c). Pub. L. 110–414, § 4(2), added subsec. (c).

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

FINDINGS

Pub. L. 110–414, § 2, Oct. 14, 2008, 122 Stat. 4341, provided that: ''Congress finds that—

''(1) mercury is highly toxic to humans, ecosystems, and wildlife;

''(2) as many as 10 percent of women in the United States of childbearing age have mercury in the blood at a level that could put a baby at risk;

''(3) as many as 630,000 children born annually in the United States are at risk of neurological problems related to mercury;

''(4) the most significant source of mercury exposure to people in the United States is ingestion of mercury-contaminated fish;

''(5) the Environmental Protection Agency reports that, as of 2004—

''(A) 44 States have fish advisories covering over 13,000,000 lake acres and over 750,000 river miles;

''(B) in 21 States the freshwater advisories are statewide; and

''(C) in 12 States the coastal advisories are statewide;

''(6) the long-term solution to mercury pollution is to minimize global mercury use and releases to eventually achieve reduced contamination levels in the environment, rather than reducing fish consumption since uncontaminated fish represents a critical and healthy source of nutrition worldwide;

''(7) mercury pollution is a transboundary pollutant, depositing locally, regionally, and globally, and affecting water bodies near industrial sources (including the Great Lakes) and remote areas (including the Arctic Circle);

''(8) the free trade of elemental mercury on the world market, at relatively low prices and in ready supply, encourages the continued use of elemental mercury outside of the United States, often involving highly dispersive activities such as artisinal [probably should be ''artisanal''] gold mining;

''(9) the intentional use of mercury is declining in the United States as a consequence of process

changes to manufactured products (including batteries, paints, switches, and measuring devices), but those uses remain substantial in the developing world where releases from the products are extremely likely due to the limited pollution control and waste management infrastructures in those countries;

''(10) the member countries of the European Union collectively are the largest source of elemental mercury exports globally;

''(11) the European Commission has proposed to the European Parliament and to the Council of the European Union a regulation to ban exports of elemental mercury from the European Union by 2011;

''(12) the United States is a net exporter of elemental mercury and, according to the United States Geological Survey, exported 506 metric tons of elemental mercury more than the United States imported during the period of 2000 through 2004; and

''(13) banning exports of elemental mercury from the United States will have a notable effect on the market availability of elemental mercury and switching to affordable mercury alternatives in the developing world.''

### § 2612. Entry into customs territory of the United States

#### (a) In general

(1) The Secretary of the Treasury shall refuse entry into the customs territory of the United States (as defined in general note 2 of the Harmonized Tariff Schedule of the United States) of any chemical substance, mixture, or article containing a chemical substance or mixture offered for such entry if—

(A) it fails to comply with any rule in effect under this chapter, or

(B) it is offered for entry in violation of section 2604 of this title, 2605 of this title, or subchapter IV, a rule or order under section 2604 of this title, 2605 of this title, or subchapter IV, or an order issued in a civil action brought under section 2604 of this title, 2606 of this title or subchapter IV.

(2) If a chemical substance, mixture, or article is refused entry under paragraph (1), the Secretary of the Treasury shall notify the consignee of such entry refusal, shall not release it to the consignee, and shall cause its disposal or storage (under such rules as the Secretary of the Treasury may prescribe) if it has not been exported by the consignee within 90 days from the date of receipt of notice of such refusal, except that the Secretary of the Treasury may, pending a review by the Administrator of the entry refusal, release to the consignee such substance, mixture, or article on execution of bond for the amount of the full invoice of such substance, mixture, or article (as such value is set forth in the customs entry), together with the duty thereon. On failure to return such substance, mixture, or article for any cause to the custody of the Secretary of the Treasury when demanded, such consignee shall be liable to the United States for liquidated damages equal to the full amount of such bond. All charges for storage, cartage, and labor on and for disposal of substances, mixtures, or articles which are refused entry or release under this section shall be paid by the owner or consignee, and in default of such payment shall constitute a lien against any future entry made by such owner or consignee.

#### (b) Rules

The Secretary of the Treasury, after consultation with the Administrator, shall issue rules for the administration of subsection (a) of this section.

(Pub. L. 94–469, title I, § 13, Oct. 11, 1976, 90 Stat. 2034; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 100–418, title I, § 1214(e)(2), Aug. 23, 1988, 102 Stat. 1156; Pub. L. 102–550, title X, § 1021(b)(4), Oct. 28, 1992, 106 Stat. 3923.)

REFERENCES IN TEXT

The Harmonized Tariff Schedule of the United States, referred to in subsec. (a), is not set out in the Code. See Publication of Harmonized Tariff Schedule note set out under section 1202 of Title 19, Customs Duties.

AMENDMENTS

1992—Subsec. (a)(1)(B). Pub. L. 102–550 substituted ''section 2604 of this title, 2605 of this title, or subchapter IV'' for ''section 2604 or 2605 of this title'' in two places and ''section 2604 of this title, 2606 of this title or subchapter IV'' for ''section 2604 or 2606 of this title''.

1988—Subsec. (a)(1). Pub. L. 100–418 substituted ''general note 2 of the Harmonized Tariff Schedule of the United States'' for ''general headnote 2 to the Tariff Schedules of the United States'' in introductory text.

EFFECTIVE DATE OF 1988 AMENDMENT

Amendment by Pub. L. 100–418 effective Jan. 1, 1989, and applicable with respect to articles entered on or after such date, see section 1217(b)(1) of Pub. L. 100–418, set out as an Effective Date note under section 3001 of Title 19, Customs Duties.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

### § 2613. Confidential information

#### (a) In general

Except as provided in this section, the Administrator shall not disclose information that is exempt from disclosure pursuant to subsection (a) of section 552 of title 5 by reason of subsection (b)(4) of that section—

(1) that is reported to, or otherwise obtained by, the Administrator under this chapter; and

(2) for which the requirements of subsection (c) are met.

In any proceeding under section 552(a) of title 5 to obtain information the disclosure of which has been denied because of the provisions of this subsection, the Administrator may not rely on section 552(b)(3) of such title to sustain the Administrator's action.

#### (b) Information not protected from disclosure

##### (1) Mixed confidential and nonconfidential information

Information that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure.

##### (2) Information from health and safety studies

Subsection (a) does not prohibit the disclosure of—

(A) any health and safety study which is submitted under this chapter with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or

(ii) any chemical substance or mixture for which testing is required under section 2603 of this title or for which notification is required under section 2604 of this title; and

(B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

This paragraph does not authorize the disclosure of any information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

**(3) Other information not protected from disclosure**

Subsection (a) does not prohibit the disclosure of—

(A) any general information describing the manufacturing volumes, expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges; or

(B) a general description of a process used in the manufacture or processing and industrial, commercial, or consumer functions and uses of a chemical substance, mixture, or article containing a chemical substance or mixture, including information specific to an industry or industry sector that customarily would be shared with the general public or within an industry or industry sector.

**(4) Bans and phase-outs**

**(A) In general**

If the Administrator promulgates a rule pursuant to section 2605(a) of this title that establishes a ban or phase-out of a chemical substance or mixture, the protection from disclosure of any information under this section with respect to the chemical substance or mixture shall be presumed to no longer apply, subject to subsection (g)(1)(E) and subparagraphs (B) and (C) of this paragraph.

**(B) Limitations**

**(i) Critical use**

In the case of a chemical substance or mixture for which a specific condition of use is subject to an exemption pursuant to section 2605(g) of this title, if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any conditions of use of the chemical substance or mixture to which the exemption does not apply.

**(ii) Export**

In the case of a chemical substance or mixture for which there is manufacture, processing, or distribution in commerce that meets the conditions of section 2611(a)(1) of this title, if the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to any other manufacture, processing, or distribution in commerce of the chemical substance or mixture for the conditions of use subject to the ban or phase-out, unless the Administrator makes the determination in section 2611(a)(2) of this title.

**(iii) Specific conditions of use**

In the case of a chemical substance or mixture for which the Administrator establishes a ban or phase-out described in subparagraph (A) with respect to a specific condition of use of the chemical substance or mixture, the presumption against protection under such subparagraph shall only apply to information that relates solely to the condition of use of the chemical substance or mixture for which the ban or phase-out is established.

**(C) Request for nondisclosure**

**(i) In general**

A manufacturer or processor of a chemical substance or mixture subject to a ban or phase-out described in this paragraph may submit to the Administrator, within 30 days of receiving a notification under subsection (g)(2)(A), a request, including documentation supporting such request, that some or all of the information to which the notice applies should not be disclosed or that its disclosure should be delayed, and the Administrator shall review the request under subsection (g)(1)(E).

**(ii) Effect of no request or denial**

If no request for nondisclosure or delay is submitted to the Administrator under this subparagraph, or the Administrator denies such a request under subsection (g)(1)(A), the information shall not be protected from disclosure under this section.

**(5) Certain requests**

If a request is made to the Administrator under section 552(a) of title 5 for information reported to or otherwise obtained by the Administrator under this chapter that is not protected from disclosure under this subsection, the Administrator may not deny the request on the basis of section 552(b)(4) of title 5.

**(c) Requirements for confidentiality claims**

**(1) Assertion of claims**

**(A) In general**

A person seeking to protect from disclosure any information that person submits

under this chapter (including information described in paragraph (2)) shall assert to the Administrator a claim for protection from disclosure concurrent with submission of the information, in accordance with such rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this subchapter.

**(B) Inclusion**

An assertion of a claim 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.

**(C) Additional requirements for claims regarding chemical identity information**

In the case of a claim under subparagraph (A) for protection from disclosure of a specific chemical identity, the claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—

(i) be consistent with guidance developed by the Administrator under paragraph (4)(A); and

(ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—

(I) that are claimed as confidential; and

(II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

**(2) Information generally not subject to substantiation requirements**

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

(A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.

(B) Marketing and sales information.

(C) Information identifying a supplier or customer.

(D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.

(F) Specific production or import volumes of the manufacturer or processor.

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

**(3) Substantiation requirements**

Except as provided in paragraph (2), 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.

**(4) Guidance**

The Administrator shall develop guidance regarding—

(A) the determination of structurally descriptive generic names, in the case of claims for the protection from disclosure of specific chemical identity; and

(B) the content and form of the statements of need and agreements required under paragraphs (4), (5), and (6) of subsection (d).

**(5) Certification**

An authorized official of a person described in paragraph (1)(A) shall certify that the statement required to assert a claim submitted pursuant to paragraph (1)(B), and any information required to substantiate a claim submitted pursuant to paragraph (3), are true and correct.

**(d) Exceptions to protection from disclosure**

Information described in subsection (a)—

(1) shall be disclosed to an officer or employee of the United States—

(A) in connection with the official duties of that person under any Federal law for the protection of health or the environment; or

(B) for a specific Federal law enforcement purpose;

(2) shall be disclosed to a contractor of the United States and employees of that contractor—

(A) if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance by the contractor of a contract with the United States for the performance of work in connection with this chapter; and

(B) subject to such conditions as the Administrator may specify;

(3) shall be disclosed if the Administrator determines that disclosure is necessary to protect health or the environment 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;

(4) shall be disclosed to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law, if such entity

has 1 or more applicable agreements with the Administrator that are consistent with the guidance developed under subsection (c)(4)(B) and ensure that the entity will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by the Administrator to safeguard the information;

(5) shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with the Administrator, subject to the conditions that—

(A) the statement of need and confidentiality agreement are consistent with the guidance developed under subsection (c)(4)(B);

(B) the statement of need shall be a statement that the person has a reasonable basis to suspect that—

(i) the information is necessary for, or will assist in—

(I) the diagnosis or treatment of 1 or more individuals; or

(II) responding to an environmental release or exposure; and

(ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

(C) the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information;

(6) shall be disclosed in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder (including any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician) if such person requests the information, subject to the conditions that such person shall—

(A) have a reasonable basis to suspect that—

(i) a medical, public health, or environmental emergency exists;

(ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or

(iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred; and

(B) if requested by a person who has a claim with respect to the information under this section—

(i) provide a written statement of need and agree to sign a confidentiality agreement, as described in paragraph (5); and

(ii) submit to the Administrator such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed;

(7) may be disclosed if the Administrator determines that disclosure is relevant in a proceeding under this chapter, subject to the condition that the disclosure is made in such a manner as to preserve confidentiality to the extent practicable without impairing the proceeding;

(8) shall be disclosed if the information is required to be made public under any other provision of Federal law; and

(9) shall be disclosed as required pursuant to discovery, subpoena, other court order, or any other judicial process otherwise allowed under applicable Federal or State law.

**(e) Duration of protection from disclosure**

**(1) In general**

Subject to paragraph (2), subsection (f)(3), and section 2607(b) of this title, the Administrator shall protect from disclosure information described in subsection (a)—

(A) in the case of information described in subsection (c)(2), until such time as—

(i) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(ii) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g); and

(B) in the case of information other than information described in subsection (c)(2)—

(i) for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator; or

(ii) if applicable before the expiration of such 10-year period, until such time as—

(I) the person that asserted the claim notifies the Administrator that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section; or

(II) the Administrator becomes aware that the information does not qualify for protection from disclosure under this section, in which case the Administrator shall take any actions required under subsections (f) and (g).

**(2) Extensions**

**(A) In general**

In the case of information other than information described in subsection (c)(2), not

later than the date that is 60 days before the expiration of the period described in paragraph (1)(B)(i), the Administrator shall provide to the person that asserted the claim a notice of the impending expiration of the period.

**(B) Request**

**(i) In general**

Not later than the date that is 30 days before the expiration of the period described in paragraph (1)(B)(i), a person reasserting the relevant claim shall submit to the Administrator a request for extension substantiating, in accordance with subsection (c)(3), the need to extend the period.

**(ii) Action by Administrator**

Not later than the date of expiration of the period described in paragraph (1)(B)(i), the Administrator shall, in accordance with subsection (g)(1)—

(I) review the request submitted under clause (i);

(II) make a determination regarding whether the claim for which the request was submitted continues to meet the relevant requirements of this section; and

(III)(aa) grant an extension of 10 years; or

(bb) deny the request.

**(C) No limit on number of extensions**

There shall be no limit on the number of extensions granted under this paragraph, if the Administrator determines that the relevant request under subparagraph (B)(i)—

(i) establishes the need to extend the period; and

(ii) meets the requirements established by the Administrator.

**(f) Review and resubstantiation**

**(1) Discretion of Administrator**

The Administrator may require any person that has claimed protection for information from disclosure under this section, whether before, on, or after June 22, 2016, to reassert and substantiate or resubstantiate the claim in accordance with this section—

(A) after the chemical substance is designated as a high-priority substance under section 2605(b) of this title;

(B) for any chemical substance designated as an active substance under section 2607(b)(5)(B)(iii) of this title; or

(C) if the Administrator determines that disclosure of certain information currently protected from disclosure would be important to assist the Administrator in conducting risk evaluations or promulgating rules under section 2605 of this title.

**(2) Review required**

The Administrator shall review a claim for protection of information from disclosure under this section and require any person that has claimed protection for that information, whether before, on, or after June 22, 2016, to reassert and substantiate or resubstantiate the claim in accordance with this section—

(A) as necessary to determine whether the information qualifies for an exemption from disclosure in connection with a request for information received by the Administrator under section 552 of title 5;

(B) if the Administrator has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section; or

(C) for any chemical substance the Administrator determines under section 2605(b)(4)(A) of this title presents an unreasonable risk of injury to health or the environment.

**(3) Period of protection**

If the Administrator requires a person to reassert and substantiate or resubstantiate a claim under this subsection, and determines that the claim continues to meet the relevant requirements of this section, the Administrator shall protect the information subject to the claim from disclosure for a period of 10 years from the date of such determination, subject to any subsequent requirement by the Administrator under this subsection.

**(g) Duties of Administrator**

**(1) Determination**

**(A) In general**

Except for claims regarding information described in subsection (c)(2), the Administrator shall, subject to subparagraph (C), not later than 90 days after the receipt of a claim under subsection (c), and not later than 30 days after the receipt of a request for extension of a claim under subsection (e) or a request under subsection (b)(4)(C), review and approve, approve in part and deny in part, or deny the claim or request.

**(B) Reasons for denial**

If the Administrator denies or denies in part a claim or request under subparagraph (A) the Administrator shall provide to the person that asserted the claim or submitted the request a written statement of the reasons for the denial or denial in part of the claim or request.

**(C) Subsets**

The Administrator shall—

(i) except with respect to information described in subsection (c)(2)(G), review all claims or requests under this section for the protection from disclosure of the specific chemical identity of a chemical substance; and

(ii) review a representative subset, comprising at least 25 percent, of all other claims or requests for protection from disclosure under this section.

**(D) Effect of failure to act**

The failure of the Administrator to make a decision regarding a claim or request for protection from disclosure or extension under this section shall not have the effect of denying or eliminating a claim or request for protection from disclosure.

**(E) Determination of requests under subsection (b)(4)(C)**

With respect to a request submitted under subsection (b)(4)(C), the Administrator shall,

with the objective of ensuring that information relevant to the protection of health and the environment is disclosed to the extent practicable, determine whether the documentation provided by the person rebuts what shall be the presumption of the Administrator that the public interest in the disclosure of the information outweighs the public or proprietary interest in maintaining the protection for all or a portion of the information that the person has requested not be disclosed or for which disclosure be delayed.

**(2) Notification**

**(A) In general**

Except as provided in subparagraph (B) and subsections (b), (d), and (e), if the Administrator denies or denies in part a claim or request under paragraph (1), concludes, in accordance with this section, that the information does not qualify for protection from disclosure, intends to disclose information pursuant to subsection (d), or promulgates a rule under section 2605(a) of this title establishing a ban or phase-out with respect to a chemical substance or mixture, the Administrator shall notify, in writing, the person that asserted the claim or submitted the request of the intent of the Administrator to disclose the information or not protect the information from disclosure under this section. The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means that allows verification of the fact and date of receipt.

**(B) Disclosure of information**

Except as provided in subparagraph (C), the Administrator shall not disclose information under this subsection until the date that is 30 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A).

**(C) Exceptions**

**(i) Fifteen day notification**

For information the Administrator intends to disclose under subsections (d)(3), (d)(4), (d)(5), and (j), the Administrator shall not disclose the information until the date that is 15 days after the date on which the person that asserted the claim or submitted the request receives notification under subparagraph (A), except that, with respect to information to be disclosed under subsection (d)(3), if the Administrator determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, no prior notification shall be necessary.

**(ii) Notification as soon as practicable**

For information the Administrator intends to disclose under paragraph (6) of subsection (d), the Administrator shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information.

**(iii) No notification required**

Notification shall not be required—

(I) for the disclosure of information under paragraphs (1), (2), (7), or (8) of subsection (d); or

(II) for the disclosure of information for which—

(aa) the Administrator has provided to the person that asserted the claim a notice under subsection (e)(2)(A); and

(bb) such person does not submit to the Administrator a request under subsection (e)(2)(B) on or before the deadline established in subsection (e)(2)(B)(i).

**(D) Appeals**

**(i) Action to restrain disclosure**

If a person receives a notification under this paragraph and believes the information is protected from disclosure under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C) the person may bring an action to restrain disclosure of the information in—

(I) the United States district court of the district in which the complainant resides or has the principal place of business; or

(II) the United States District Court for the District of Columbia.

**(ii) No disclosure**

**(I) In general**

Subject to subsection (d), the Administrator shall not disclose information that is the subject of an appeal under this paragraph before the date on which the applicable court rules on an action under clause (i).

**(II) Exception**

Subclause (I) shall not apply to disclosure of information described under subsections (d)(4) and (j).

**(3) Request and notification system**

The Administrator, in consultation with the Director of the Centers for Disease Control and Prevention, shall develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d).

**(4) Unique identifier**

The Administrator shall—

(A)(i) 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; and

(ii) apply that identifier consistently to all information relevant to the applicable chemical substance;

(B) annually publish and update a list of chemical substances, referred to by their unique identifiers, for which claims to pro-

tect the specific chemical identity from disclosure have been approved, including the expiration date for each such claim;

(C) ensure that any nonconfidential information received by the Administrator with respect to a chemical substance included on the list published under subparagraph (B) while the specific chemical identity of the chemical substance is protected from disclosure under this section identifies the chemical substance using the unique identifier; and

(D) for each claim for protection of a specific chemical identity that has been denied by the Administrator or expired, or that has been withdrawn by the person who asserted the claim, and for which the Administrator has used a unique identifier assigned under this paragraph to protect the specific chemical identity in information that the Administrator has made public, clearly link the specific chemical identity to the unique identifier in such information to the extent practicable.

**(h) Criminal penalty for wrongful disclosure**

**(1) Individuals subject to penalty**

**(A) In general**

Subject to subparagraph (C) and paragraph (2), an individual described in subparagraph (B) shall be fined under title 18 or imprisoned for not more than 1 year, or both.

**(B) Description**

An individual referred to in subparagraph (A) is an individual who—

(i) pursuant to this section, obtained possession of, or has access to, information protected from disclosure under this section; and

(ii) knowing that the information is protected from disclosure under this section, willfully discloses the information in any manner to any person not entitled to receive that information.

**(C) Exception**

This paragraph shall not apply to any medical professional (including an emergency medical technician or other first responder) who discloses any information obtained under paragraph (5) or (6) of subsection (d) to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient.

**(2) Other laws**

Section 1905 of title 18 shall not apply with respect to the publishing, divulging, disclosure, or making known of, or making available, information reported to or otherwise obtained by the Administrator under this chapter.

**(i) Applicability**

**(1) In general**

Except as otherwise provided in this section, section 2607 of this title, or any other applicable Federal law, the Administrator shall have no authority—

(A) to require the substantiation or resubstantiation of a claim for the protection from disclosure of information reported to or otherwise obtained by the Administrator under this chapter prior to June 22, 2016; or

(B) to impose substantiation or resubstantiation requirements, with respect to the protection of information described in subsection (a), under this chapter that are more extensive than those required under this section.

**(2) Actions prior to promulgation of rules**

Nothing in this chapter prevents the Administrator from reviewing, requiring substantiation or resubstantiation of, or approving, approving in part, or denying any claim for the protection from disclosure of information before the effective date of such rules applicable to those claims as the Administrator may promulgate after June 22, 2016.

**(j) Access by Congress**

Notwithstanding any limitation contained in this section or any other provision of law, all information reported to or otherwise obtained by the Administrator (or any representative of the Administrator) under this chapter shall be made available, upon written request of any duly authorized committee of the Congress, to such committee.

(Pub. L. 94–469, title I, § 14, Oct. 11, 1976, 90 Stat. 2034; renumbered title I, Pub. L. 99–519, § 3(c)(1), Oct. 22, 1986, 100 Stat. 2989; amended Pub. L. 114–182, title I, § 11, June 22, 2016, 130 Stat. 481.)

AMENDMENTS

2016—Pub. L. 114–182 amended section generally. Prior to amendment, section related to disclosure of data.

EFFECTIVE DATE

Section effective Jan. 1, 1977, see section 31 of Pub. L. 94–469, set out as a note under section 2601 of this title.

## § 2614. Prohibited acts

It shall be unlawful for any person to—

(1) fail or refuse to comply with any requirement of this subchapter or any rule promulgated, order issued, or consent agreement entered into under this subchapter, or any requirement of subchapter II or any rule promulgated or order issued under subchapter II;

(2) use for commercial purposes a chemical substance or mixture which such person knew or had reason to know was manufactured, processed, or distributed in commerce in violation of section 2604 or 2605 of this title, a rule or order under section 2604 or 2605 of this title, or an order issued in action brought under section 2604 or 2606 of this title;

(3) fail or refuse to (A) establish or maintain records, (B) submit reports, notices, or other information, or (C) permit access to or copying of records, as required by this chapter or a rule thereunder; or

(4) fail or refuse to permit entry or inspection as required by section 2610 of this title.

(Pub. L. 94–469, title I, § 15, Oct. 11, 1976, 90 Stat. 2036; renumbered title I and amended Pub. L. 99–519, § 3(b)(1), (c)(1), Oct. 22, 1986, 100 Stat. 2988, 2989; Pub. L. 114–182, title I, § 19(*l*), June 22, 2016, 130 Stat. 508.)

## CERTIFICATE OF SERVICE

I hereby certify that on March 6, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system.

All parties to the case have counsel who are registered CM/ECF users and service will be accomplished through the appellate CM/ECF system. Those counsel served by the appellate CM/ECF system include:

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March 6, 2018

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