ORAL ARGUMENT NOT YET SCHEDULED

No. 17-1201

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND, *et al.*,

Petitioners,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, *et al.*,

Respondents.

Petition for Review of Final Administrative Action
of the United States Environmental Protection Agency

(FINAL FORM) BRIEF OF INTERVENORS IN SUPPORT OF RESPONDENT UNITED STATES ENVIRONMENTAL PROTECTION AGENCY

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

Pursuant to Circuit Rule 28(a), the American Chemistry Council, American Coatings Association, American Coke and Coal Chemicals Institute, American Forest & Paper Association, American Fuel & Petrochemical Manufacturers, American Petroleum Institute, Chamber of Commerce of the United States of America, EPS Industry Alliance, IPC International, Inc., National Association of Chemical Distributors, National Association of Manufacturers, National Mining Association, Polyurethane Manufacturers Association, and Society of Chemical Manufacturers and Affiliates certify:

(A) Parties and Amici.

Because this case involves direct review of a final agency action, the requirement to furnish a list of parties, intervenors, and *amici* that appeared below is inapplicable.

(B) Rulings Under Review.

References to the ruling at issue appear in the Brief for Respondent.

(C) Related Cases.

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

/S/ PETER D. KEISLER
PETER D. KEISLER

RULE 26.1 DISCLOSURE STATEMENT

Pursuant to Rule 26.1 of the Federal Rules of Appellate Procedure and Circuit Rule 26.1, the American Chemistry Council, American Coatings Association, American Coke and Coal Chemicals Institute, American Forest & Paper Association, American Fuel & Petrochemical Manufacturers, American Petroleum Institute, Chamber of Commerce of the United States of America, EPS Industry Alliance, IPC International, Inc., National Association of Chemical Distributors, National Association of Manufacturers, National Mining Association, Polyurethane Manufacturers Association, and Society of Chemical Manufacturers and Affiliates submit this disclosure statement.

The American Chemistry Council ("ACC") represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier, and safer. ACC is committed to improved environmental, health and safety performance through Responsible Care®, common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a $768 billion enterprise and a key element of the nation's economy. It is the nation's largest exporter, accounting for fourteen percent of all U.S. exports. Chemistry companies are among the largest investors in research and development in the United States. ACC states that it is a

trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

American Coatings Association ("ACA") is the national nonprofit trade association working to advance the paint and coatings industry and the 287,000 professionals who work in it. The organization represents paint and coatings manufacturers, raw materials suppliers, distributors, and technical professionals who produce over $30 billion in paint and coating product shipments. ACA members use and produce chemicals subject to regulation under TSCA, including the Inventory Reset Rule. ACA states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

American Coke and Coal Chemicals Institute ("ACCCI") is an association for the metallurgical coke and coal chemicals industry. ACCCI members include U.S. merchant coke producers and integrated steel companies with coke production capacity, as well as the companies producing coal chemicals in the U.S. ACCCI states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

American Forest & Paper Association ("AF&PA") serves the sustainable pulp, paper, packaging, tissue and wood products manufacturing industry in the

United States. AF&PA member companies make products essential for everyday life from renewable and recyclable resources. The forest products industry accounts for approximately four percent of the total United States manufacturing Gross Domestic Product, manufactures over $200 billion in products annually, and employs approximately 900,000 men and women. AF&PA states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

American Fuel & Petrochemical Manufacturers ("AFPM") is a national trade association representing approximately 400 companies that encompass virtually all U.S. refining and petrochemical manufacturing capacity. AFPM states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly traded corporation owns ten percent or more of its stock.

The American Petroleum Institute ("API") is a national trade association with over 625 corporate members that represents all aspects of America's oil and natural gas industry, including producers, refiners, suppliers, marketers, pipeline operators and marine transporters, as well as service and supply companies that support all segments of the industry. API's mission is to promote safety across the industry globally and to influence public policy in support of a strong, viable U.S. oil and natural gas industry. API negotiates with regulatory agencies, represents the industry in legal proceedings, participates in coalitions, and works in partnership with other

associations to achieve its members' public policy goals. API states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

The Chamber of Commerce of the United States of America ("the Chamber") is the world's largest business federation, representing 300,000 direct members and indirectly representing the interests of more than three million companies and professional organizations of every size, in every industry sector, and from every region of the country. The Chamber states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

EPS Industry Alliance represents manufacturers of expanded polystyrene ("EPS"). EPS and the chemistries used to produce it are subject to TSCA jurisdiction, including the Inventory Reset Rule. EPS states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

IPC International, Inc., doing business as IPC - Association Connecting Electronics Industries ("IPC"), is a not-for-profit association consisting of 4,200 member facilities that manufacture electronics or supply equipment and materials to industries manufacturing electronics. The majority of IPC members use chemicals to manufacture products or sell products containing chemicals, but a small

percentage manufacture and/or distribute chemicals to electronics manufacturers. As manufacturers, distributors and users of chemicals, IPC members are affected by TSCA rulemaking, including the Inventory Reset Rule. The development and manufacture of electronics is directly affected by restrictions on the chemicals used to manufacture them and thus effect IPC members. IPC states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

National Association of Chemical Distributors ("NACD") is an association of chemical distributors and their supply-chain partners. NACD's members process, formulate, blend, repackage, warehouse, transport, and market chemical products for over 750,000 customers. The chemical distribution industry represented by NACD employs over 70,000 people and generates $5.14 billion in tax revenue for local communities. The products distributed by NACD members are subject to EPA's TSCA jurisdiction, including the Inventory Reset Rule. NACD states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in every industrial sector and in all 50 states. Manufacturing employs

more than 12 million men and women, contributes $2.25 trillion to the U.S. economy annually, has the largest economic impact of any major sector and accounts for more than three-quarters of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community, whose members manufacture, use, and/or distribute chemicals subject to EPA's TSCA jurisdiction, including the Inventory Reset Rule. The NAM states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

National Mining Association ("NMA") is a national trade association that represents the interests of the mining industry—including the producers of most of America's coal, metals, and industrial, and agricultural minerals, as well as the manufacturers of mining and mineral processing machinery, equipment, and supplies—before Congress, the administration, federal agencies, the judiciary, and the media. NMA has approximately 270 members, many of which manufacture, process, and/or use chemical substances subject to TSCA, including the Inventory Reset Rule. NMA states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

Polyurethane Manufacturers Association ("PMA") is the association dedicated to the advancement of the cast polyurethane industry. Its members include processors, suppliers and other members in the cast urethane industry. The chemicals that are used to manufacture polyurethanes are substances subject to EPA's TSCA jurisdiction, including the Inventory Reset Rule. PMA states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

SOCMA—Society of Chemical Manufacturers and Affiliates ("SOCMA") is the U.S.-based trade association dedicated solely to the specialty chemical industry. SOCMA's 200 members produce intermediates, specialty chemicals and ingredients used to develop a wide range of industrial, commercial and consumer products. SOCMA's manufacturing members all produce chemicals subject to regulation under TSCA, including the Inventory Reset Rule, and all of its members could be impacted by EPA's actions under the Rule. SOCMA states that it is a trade association for purposes of Circuit Rule 26.1(b); that it has no parent company; and that no publicly-held company has a ten percent or greater ownership interest.

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GLOSSARY

ACC	American Chemistry Council
AFPM	American Fuel & Petrochemical Manufacturers
API	American Petroleum Institute
CBI	Confidential Business Information
EDF	Environmental Defense Fund
EPA	U.S. Environmental Protection Agency
Reset Rule	TSCA Inventory Notification (Active-Inactive Requirements), 82 FR 37,520 (Aug. 11, 2017)
Review Plan	Future rule to be promulgated pursuant to TSCA §8(b)(4)(C), 15 U.S.C. §2607(b)(4)(C)
TSCA	Toxic Substances Control Act, 15 U.S.C. §2601 *et seq.*

STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in the Brief for Respondent EPA and the Brief for Petitioner.

INTRODUCTION

Since 1976, the Toxic Substances Control Act ("TSCA" or the "Act") has required the Environmental Protection Agency ("EPA") to maintain an inventory of chemicals in U.S. commerce ("Inventory"). The Inventory identifies more than 85,000 chemical substances, separately listing those chemical identities that are publicly available and those that are confidential.

Intervenors represent a cross-section of industry that manufactures, imports, processes, or uses these essential chemicals.[1] For four decades, manufacturers and processors have followed EPA procedures to add to the Inventory or use listed chemicals. These include procedures to notify EPA of an intent to manufacture or process a chemical already listed as confidential by relying on an existing confidentiality claim. EPA did not require the submission of duplicate confidentiality claims and established no procedure for such claims. Industry has long relied on this established practice to protect confidential business information ("CBI"). Presently, the Inventory includes approximately 18,000 confidential chemical identities.

In June 2016, Congress amended TSCA in the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Amendments"). A key provision in the Amendments directed EPA to update the Inventory by dividing it between chemicals

[1] *See* Michael Walls Decl., Mot. for Leave to Intervene of American Chemistry Council, *et al.*, ECF No. 1696256 (Oct. 2, 2017) ("Walls Decl.").

that are active and inactive in commerce. 15 U.S.C. §2607. An updated Inventory is necessary to implement new regulatory programs mandated by TSCA.

Following Congress' direction, EPA promulgated the Reset Rule at issue in this appeal.[2] The Reset Rule established procedures for manufacturers and processors to report to EPA on chemicals manufactured or processed in the ten years before the Amendments and to maintain an existing claim for protection against disclosure of a confidential chemical identity.

Petitioner, however, seeks to rewrite the Amendments to require immediate disclosure of decades of CBI and derail EPA's sensible regulatory framework. According to Petitioner, TSCA must be read to potentially void thousands of well-established confidentiality claims without prior review, impose an unworkable procedural framework for evaluating confidentiality claims, and reverse 40 years of EPA practice to create a reporting requirement for chemicals manufactured or processed solely for export. EPA properly rejected this extreme and atextual reading of TSCA, and this Court should deny the petition for review.

STATEMENT OF THE CASE

Respondent EPA has provided a complete statement of the case. EPA Br. 4-13. We write to highlight that, at its core, this case is about maintaining protection

[2] JA123-47, TSCA Inventory Notification (Active-Inactive) Requirements, 82 FR 37,520 (Aug. 11, 2017).

over highly confidential chemical identities and related CBI provided to EPA under TSCA.

Chemistry in our economy. The U.S. chemistry business is a $768 billion enterprise. It creates 25% of our gross domestic product, accounts for 14% of exports, produces 15% of the world's chemicals, and supports millions of jobs in businesses that manufacture, process, formulate, distribute, use, and rely on chemicals.[3] Virtually every sector of the U.S. economy relies in some way on chemicals regulated by EPA under TSCA.

Trade secrets and CBI. Companies have invested billions of dollars in research and development to bring chemicals to the U.S. market.[4] The specific "chemical identity" of these chemicals refers to the precise molecular formulation of a chemical substance.[5] This includes information on chemical structure, composition, manufacturing process, and raw materials.[6] These specific chemical identities are

[3] *See* Walls Decl., *supra* ¶4 (chemistry is the building block for 96 percent of all manufactured goods).

[4] *See* Testimony of Craig Morrison on Behalf of ACC Before the Subcommittee on Environment & the Economy, U.S. House of Representatives Regarding Sections 5 & 14 of the Toxic Substances Control Act at 3 (July 11, 2013).https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg86392/pdf/CHRG-113hhrg86392.pdf ("Morrison Testimony").

[5] 15 U.S.C. §2602(2).

[6] Letter from M. Walls to Hon. J. Shimkus with Responses of ACC to Questions for the Record at 2 (Aug. 14, 2013), https://www.gpo.gov/fdsys/pkg/CHRG-113hhrg86392/pdf/CHRG-113hhrg86392.pdf ("ACC Response").

often highly confidential trade secrets.[7] Related commercial and financial information that would result in competitive harm if disclosed is also CBI, including "information that describes or reveals how a substance, mixture, or article is manufactured, processed, or distributed."[8] Maintaining confidentiality is critical, as "the innovation in chemistry depends on protection of confidential chemical identities, which are among the most valuable intellectual property in the chemical industry."[9] Companies derive substantial competitive value from information maintained as confidential under TSCA by having exclusive use of it in their own businesses and by being able to selectively and securely share it with customers or others. Disclosure would unfairly make the fruits of investments available to those who did not make similar investments.

Confidentiality under TSCA. Since its enactment, TSCA has required chemical manufacturers to share confidential information with EPA. However, TSCA prohibits EPA from disclosing that information except in certain specific circumstances, and EPA has long followed an established process to protect highly confidential chemical identities and other CBI from public disclosure. *See* EPA Br. 4-

[7] *See* Morrison Testimony, *supra* at 10; ACC Response, *supra* at 2.

[8] *See* ACC Response, *supra* at 5.

[9] Morrison Testimony, *supra* at 10; *see* Walls Decl., *supra* ¶18 ("Protecting confidential business information has critical commercial value to ACC members and promotes chemical innovation and development."); *e.g.*, JA056, Indep. Lubricant Mfrs. Ass'n Comments at 4 ("Trade secrets and formulations are the life-blood of chemical manufacturers and processors.").

7, 19-21. Before the Amendments, TSCA §5 required a manufacturer of a new chemical substance for a non-exempt commercial purpose to provide EPA with a premanufacture notice (commonly referred to as a "PMN").[10] 15 U.S.C. §2604(a)(1)(A)(i). The premanufacture notice supplied relevant data, including the chemical identity, and provided the basis for maintaining any information as confidential if warranted. 15 U.S.C. §2604(d); 40 C.F.R. §§720.22, 720.85. Unless EPA stated an objection within 90 days, the manufacturer could then produce the chemical, while EPA maintained the confidential chemical identity on the confidential portion of the Inventory and listed the chemical by generic name on the public Inventory. 15 U.S.C. §2604(d)(2); 40 C.F.R. §720.85(a)(4).[11] Thereafter, any manufacturer that wanted to manufacture a chemical already on the confidential Inventory did not need to submit anything further. If unsure whether its specific chemical was already listed, the manufacturer could choose to submit a "*bona fide* notice of intent to manufacture" in order to obtain a written determination from EPA that the chemical was on the confidential portion of the Inventory and may be used. 40 C.F.R. §720.25. If EPA confirmed the substance was listed, the inquiry was complete, as the substance was not new and thus did not require a premanufacture

[10] Separately, TSCA §5 requires manufacturers *and* processors to provide notice of a significant new use of an existing chemical. 15 U.S.C. §2604(a)(1)(A)(ii).

[11] ACC Response, *supra* at 6 (generic name permits "the public to have sufficient knowledge of the chemical structure as to allow an understanding of the intrinsic properties").

notice. 40 C.F.R. §§720.22, 720.25. EPA never required *bona fide* submissions or a duplicate confidentiality claim for follow-on companies to manufacture the same confidential chemical. *See* 40 C.F.R. §§720.25 and 720.80(a) (2015) (pre-Amendments regulations establishing a process only for asserting confidentiality over information in a new chemical submission).[12]

2016 Amendments. In the Amendments, Congress created a process to evaluate the risk of priority chemicals under rules to be established under TSCA §6. 15 U.S.C. §§2604, 2605. To facilitate the review, in TSCA §8, Congress directed EPA to update the Inventory. 15 U.S.C. §2607(b). The goal of these integrated steps—Inventory reset, prioritization, risk evaluation—is to provide the public with further assurance regarding the safety of chemicals under the conditions of use.

EPA promulgated three related rules to implement the process mandated by the 2016 Amendments.[13] The Reset Rule under review here is one of them. As detailed in the previous Administration's proposal,[14] and then retained in the agency's final rule, this rule directs chemical manufacturers and permits processors to provide notice to EPA of the chemicals manufactured in commerce during the ten years

[12] *See generally* https://www.epa.gov/tsca-inventory/about-tsca-chemical-substance-inventory (describing process) (last updated Sept. 14, 2016).

[13] *See also* Procedures for Prioritization of Chemicals for Risk Evaluation, 82 FR 33,753 (July 20, 2017); Procedures for Chemical Risk Evaluation, 82 FR 33,726 (July 20, 2017).

[14] *See* JA001-15, Proposed Reset Rule, 82 FR 4,255 (Jan. 13, 2017).

preceding the Amendments. 40 C.F.R. §710.25(a)-(b). Also reflected in both the proposed and final Reset Rule,[15] any manufacturer or processor also may notify EPA that it seeks to maintain an existing claim for protection of a specific chemical identity that is listed on the confidential portion of the Inventory. *Id.* §710.37(a). In this way, EPA will be able to reset the existing Inventory into active/inactive chemicals and further divide active chemicals into those that are public and those claimed as confidential.

The Amendments require EPA to review all claims to maintain confidentiality over specific chemical identities for existing chemicals. Congress directed EPA to create a process for claimants to substantiate confidential chemical identity protection claims and to review each such claim once it completes the Inventory reset. 15 U.S.C. §2607(b)(4)(C) ("Review Plan"). The Review Plan will set a deadline for claimants to submit substantiation. *Id.* §2607(b)(4)(D)(i). EPA has five years after it resets the Inventory to complete its reviews, although it may extend that by up to two years based on the number of claims and available resources. *Id.* §2607(b)(4)(E). Congress also allowed claimants to substantiate their claims before the deadline in the Review Plan. *Id.* §2607(b)(4)(D)(i). Following that direction, in the Reset Rule, EPA has also provided detailed requirements for those manufacturers or processors who provide substantiation early. 40 C.F.R. §710.37.

[15] *Compare* JA013-14, 82 FR at 4267-68 (proposal) *with* JA146, 82 FR at 37,543 (final).

SUMMARY OF THE ARGUMENT

Petitioner has raised four basic arguments. All should be rejected.

First, Petitioner's claim that only the initial manufacturer can maintain an existing claim of confidentiality over a chemical's identity should be rejected. The language of TSCA §8 is clear; Congress authorized "*any*" manufacturer or processor to maintain *an* existing claim. 15 U.S.C. §2607 (emphasis added). The Reset Rule faithfully implements the statute's plain language. Additionally, EPA acted reasonably in rejecting Petitioner's approach as inconsistent with EPA's decades-long practice to protect chemical identities on the Inventory as CBI; Petitioner's approach would potentially result in immediate disclosure of highly confidential chemical identities in which companies have legitimate confidentiality interests without prior review. EPA properly rejected that extreme position.

Second, Petitioner's contention that the Reset Rule violated substantive and procedural requirements in TSCA §14 is also without merit. Petitioner claims that EPA erred in setting requirements to substantiate a confidentiality claim, arguing that EPA's requirement to certify that a chemical identity was not readily discoverable through "reverse engineering" was insufficient to meet TSCA §14's substantiation requirements. Petitioner lacks standing to bring this challenge, as it cannot show how this certification requirement causes it injury. Regardless, EPA's approach is reasonable and entitled to deference.

Petitioner relatedly claims the Reset Rule failed to comply with other procedural aspects of TSCA §14, but can point to nothing in the Reset Rule indicating that EPA has disregarded the statutory requirements. EPA followed Congress' specific direction in TSCA §8 with respect to "all" existing confidentiality claims for chemical identities, and its application of existing CBI regulations to all other confidential claims submitted under the Reset Rule is fully compatible with the procedural requirements of TSCA §14. In all events, Petitioner lacks standing to bring this claim because it cannot establish it suffers any informational injury; public disclosure of the information at issue could only come after other final agency actions that are not the subject of the Reset Rule challenged here.

Third, Petitioner's assertion that EPA must assign and disclose confidential chemicals' unique identifiers under TSCA §8(b)(7) in the Reset Rule is not ripe because EPA has not yet taken final action on this requirement. 15 U.S.C. §2607(b)(7). TSCA does not require EPA to address the unique identifiers when it resets the Inventory. Rather, TSCA §§8 and 14(g)(4) first require EPA to establish the Review Plan, decide which confidentiality claims to sustain and then implement a system to assign the unique identifiers. 15 U.S.C. §§2607, 2613(g)(4). Thus, EPA's decision not to assign unique identifiers now is well supported by the statute.

Fourth, Petitioner's claim that EPA must include export-only chemicals in the Reset Rule process also should be rejected. In TSCA §8(b)(4), 15 U.S.C. §2607(b)(4), Congress specifically directed EPA to require notification of chemicals manufactured

or processed for a "nonexempt commercial purpose," as defined by EPA. EPA reasonably exercised its discretion to define "nonexempt commercial purpose" to exclude otherwise exempt export-only chemicals. Export-only chemicals have never been required to be on the Inventory, and excluding them from the Reset Rule process avoids the illogical result whereby current but not future export-only chemicals would be listed.

If the Court were to find any of EPA's action inadequate in some respect, the proper remedy would be a remand for additional explanation, not vacatur. All of the regulatory actions taken by EPA in this proceeding were within its statutory authority. Vacatur would risk unfair, direct, and irreparable harm to an industry that has long relied on the protections established by EPA.

ARGUMENT

I. The Reset Rule properly authorizes *any* manufacturer or processor to maintain an existing confidentiality claim.

Congress spoke plainly in allowing *any* manufacturer or processor to request to maintain *an* existing confidentiality claim for the specific chemical identity of a chemical in the Inventory. 15 U.S.C. §2607(b)(4)(B). Hence, EPA properly implemented that statutory directive by providing that a manufacturer or processor of a chemical may maintain an existing confidentiality claim even if it is not the entity that originally asserted the claim. But even if there were ambiguity, EPA's

interpretation is reasonable, and Petitioner's interpretation would unreasonably bar legitimate confidentiality claims.

A. TSCA expressly provides that any manufacturer or processor may request to maintain an existing confidentiality claim.

TSCA §8(b)(4)(B) states that "[i]n promulgating [the Reset Rule], [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" to submit a notice that the chemical is active and that includes such request. 15 U.S.C. §2607(b)(4)(B)(emphasis added). EPA followed this direction and allowed *any* manufacturer or processor to submit a request to maintain *an* existing claim of confidentiality as part of its notice. *See* 40 C.F.R. §§710.25, 710.37(a).

Contrary to Petitioner's assertion, this statutory language is clear. "Any" manufacturer or processor in TSCA §8 means "any." *See New York v. EPA*, 443 F.3d 880, 885 (D.C. Cir. 2006) ("the word 'any' has an expansive meaning, that is, one or some indiscriminately of whatever kind"(citation omitted)). Petitioner asserts (at 31) that only the manufacturer or processor that first made a confidentiality claim may maintain a claim. That would read "any" out of the statute, violating a cardinal principle of statutory construction. *Pub. Citizen, Inc. v. Rubber Mfr. Ass'n*, 533 F.3d 810, 815-17 (D.C. Cir. 2008).

Further, the word "maintain" is likewise not limiting in the way Petitioner asserts. Petitioner contends (at 31) a person can "maintain" only a claim which that

person made, and no one else's. This reading ignores the term's ordinary meaning. *Prime Time Int'l Co. v. Vilsack*, 599 F.3d 678, 683 (D.C. Cir. 2010) (undefined terms are given their ordinary meaning). To "maintain" is to "cause or enable a condition or state of affairs to continue." *Oxford American Dictionary* 607 (3d ed. 2010). A person can "maintain" a state of affairs regardless of whether he or she initiated such state of affairs. *E.g.*, *Darrell Andrews Trucking Inc. v. Fed. Motor Carrier Safety Admin.*, 296 F.3d 1120, 1123, 1127 (D.C. Cir. 2002) (upholding requirement that agency "maintain" in usable condition supporting documentation it receives).

Moreover, Congress provided that "any" manufacturer or processor may maintain "*an* existing claim." "An" is an "indefinite article," *Am. Bus. Ass'n v. Slater*, 231 F.3d 1, 4-5 (D.C. Cir. 2000) ("a" or "an" has "indefinite or generalizing force"), not a possessive form limiting the claims covered. Congress could have narrowed the scope of permissible requests to maintain protection by referring to "its" or "such manufacturer's or processor's" claim, but it did not. *See Smith v. United States*, 508 U.S. 223, 239-40 (1993) ("[i]mposing a more restrictive reading of the [statutory] phrase ... does violence not only to the structure and language of the statute, but to its purpose as well"); *W. Minn. Mun. Power Agency v. FERC*, 806 F.3d 588, 592, 596 (D.C. Cir. 2015) (the terms "states" and "municipalities" with no qualifying language include all states and municipalities). Petitioner's argument is consistent with neither the statutory language nor EPA's historical administration of the Inventory.

Petitioner nonetheless contends (at 32-33) that Congress implicitly restricted who may "maintain an existing claim" under TSCA §8 to the initial claimant, because confidentiality claims for *new* claims under §14 of TSCA are "person-specific." But that provision in TSCA §14 only underscores that Congress knew how to restrict a confidentiality request to "that person's" own claim, something Congress conspicuously did *not* do for existing claims in TSCA §8. 15 U.S.C. §2607. Specifically, in TSCA §14(c)(1)(A) Congress provided that "[a] *person* seeking to protect from disclosure any information *that person* submits" to support a new claim must follow certain rules. 15 U.S.C. §2613(c)(1)(A)(emphases added). By contrast, TSCA §8 contains *no* person-specific language. As such, Congress clearly distinguished the new claims process (TSCA §14) from the existing claims process (TSCA §8). *E.g.*, *Hamdan v. Rumsfeld*, 548 U.S. 557, 578 (2006) ("a negative inference may be drawn from the exclusion of language from one statutory provision that is included in other provisions of the same statute.").[16]

Lacking a statutory basis, Petitioner then moves far afield from its alleged plain language argument by claiming to draw on "broader precedent" related to trade secrets and CBI. Pet. Br. 34-36. Petitioner appears to argue that if a confidential chemical identity is shared or becomes known by anyone other than the initial

[16] As explained in greater detail below, this distinction tracks how EPA historically processed confidentiality claims. *See* pp. 28-29, *infra*.

claimant, full public disclosure is then required. Thus, Petitioner argues, Congress must have meant to permit only the initial claimant (or its successor) to maintain an existing claim.

Petitioner's contention misunderstands how the chemical industry conducts business. Manufacturers and processors routinely rely on existing confidentiality claims asserted by a different entity. EPA recognizes this in its premanufacture notice regulations. 40 C.F.R. §720.85(b)(2)(i); EPA Br. 20. Moreover, as EPA also recognizes, it is common commercial practice for private parties to enter into non-disclosure agreements drafted specifically to allow for the exchange of confidential information. 40 C.F.R. §710.37(c)(1)(iii) (referring to "non-disclosure agreements" as precautions taken to protect confidentiality). That allows the initial manufacturer to benefit from its innovation by licensing it to others, while still protecting its investment, and allows a licensee to benefit as well. *E.g.*, JA081, Int'l Fragrance Ass'n N. Am. Comments at 5 (industry's "complex, international value chains"); JA085, Am. Coatings Ass'n Comments at 3 (company may have sold rights to listed chemical to another company). Yet, such arrangements in no way diminish the right to maintain a confidentiality claim. *See, e.g.*, *Soghoian v. Office of Mgmt. & Budget*, 932 F. Supp. 2d 167, 176 (D.D.C. 2013) (upholding confidentiality of information exchanged through confidentiality agreements); *Ctr. for Auto Safety v. NHTSA*, 93 F. Supp. 2d 1, 18

(D.D.C. 2000) (same).[17] Otherwise, a chemical manufacturer or processor would not be able to share any confidential information with any partner or customer without risking losing all rights to protect its valuable investment.

B. EPA's interpretation is reasonable and should be sustained.

Even if TSCA were not clear, EPA's interpretation of its TSCA authority is entitled to deference. EPA reasonably interpreted the Amendments to create a two-step process for existing claims: (1) create an updated inventory that designates active chemicals that manufacturers and processors seek to maintain as confidential; and (2) leave for the Review Plan to identify what and when substantiation would be needed and how EPA would conduct its review. *See* JA130, 82 FR at 37,527. In this way, EPA permitted any manufacturer or processor to hit the "pause button" and ensure EPA maintains protections from disclosure until EPA completes its review. This interpretation matches the staged and orderly approach Congress established in TSCA §8 for maintaining, substantiating, and reviewing existing confidentiality claims. 15 U.S.C. §2607(b)(4)(A)-(B) (Reset Rule identifies chemicals for Inventory, including which are confidential), (C)-(D) (Review Plan sets process for reviewing

[17] If Petitioner's contention is that multiple requests to maintain confidentiality could indicate that the chemical identity is no longer confidential, Pet. Br. 41-42, that is a case-specific issue which EPA can assess when it ultimately evaluates a particular claim. 40 C.F.R. §710.37(c)(1)(iii). There is no reason to adopt an arbitrary restriction on who may "maintain" confidentiality claims because some claims may ultimately be found to be invalid.

confidentiality claims), and (E) (a five to seven year timeline for EPA to complete its reviews); *see* JA130, 82 FR at 37,527.

Petitioner advances three arguments against this approach, but none has merit. *First*, it asserts (at 37-41) that all manufacturers or processors were "legally required" to have themselves asserted a confidentiality claim previously if they agreed with an already-existing confidentiality designation or risked "waiving" any such claim forever. As EPA correctly notes (at 27-28), EDF did not raise this issue in its comments and, thus, has waived this argument. Even if such a past legal requirement existed—and it did not—that would be of no moment. EPA's interpretation of TSCA §8(b)(4)(b)(ii), 15 U.S.C. §2607(b)(4)(B)(ii), to allow "any" manufacturer or processor to "maintain an existing claim" is a permissible textual reading, whether or not the claim could or should have been raised earlier. *See* EPA Br. 10-14.

Regardless, the requirement Petitioner wishes had been imposed has never existed.[18] As detailed, EPA's long-standing premanufacture notice and "bona-fide notice of intent" process required only the *initial manufacturer* of a chemical to provide

[18] The very regulatory preamble Petitioner cites (at 40) supports EPA's approach. The reference establishes a person may claim confidentiality over information he or she submits, *and* confirms a person need not submit information EPA already possesses—such as the basis for an existing confidential designation of a chemical identity. 42 FR 64,572, 64,573-574 (Dec. 23, 1977) ("EPA believes that Congress did not intend manufacturers to be required to furnish EPA pre-manufacture notification on" existing confidential chemical identities; "EPA will tell the inquiring manufacturer whether the chemical substance is included on the inventory as a confidential identity, and therefore, whether he must submit a TSCA pre-manufacture notification.").

a notice in which it could assert confidentiality; there is no corresponding premanufacture notice requirement for processors, as processors by definition do not manufacture chemicals. *See* 40 C.F.R. §§720.3(aa)-(bb) (defining processor as a person who prepares "a chemical substance or mixture, *after its manufacture*, for distribution in commerce") (emphasis added). Thus, subsequent manufacturers and processors rely on the claim asserted through the premanufacture notice that was submitted by the initial manufacturer. JA130, 82 FR at 37,527 ("persons [who] did not originally report the chemical identity to EPA ... were not in a position to assert a CBI claim for that chemical identity"); *see* EPA Br. 19-21, 28-29.

Congress is presumed to understand, and legislate in light of, the applicable "regulatory backdrop." *Coal. for Common Sense in Gov't Procurement v. United States,* 707 F.3d 311, 318 (D.C. Cir. 2013). That regulatory history is dispositive here. Although Petitioner repeatedly asserts (at 33-36) that a confidentiality claim must be "person-specific," it concedes (at 41) that the actual regulatory practice under TSCA at the time the Amendments were enacted was the opposite and that it permitted subsequent manufacturers and processors to rely upon existing confidentiality designations. Because subsequent manufacturers and processors were never required to duplicate confidentiality claims that had already been made and implemented, it is eminently reasonable for EPA to construe TSCA to enable them to "maintain" those claims now pending further EPA review.

Second, Petitioner challenges EPA's reliance on the fact that over the course of 40 years there have been many business transactions among manufacturers and processors. Pet. Br. 41-43. Petitioner agrees a successor in interest should be covered under the definition of "any manufacturer or processor," but argues the definition should not extend beyond that. *Id.* at 41. But Petitioner points to nothing in the statute (or logic) that would suggest that successors in interest should be able to maintain a claim but other entities that had a legitimate basis for doing so (such as manufacturing pursuant to a non-disclosure agreement) cannot maintain a claim. EPA also reasonably recognized that manufacturers and processors who did not originally report a chemical identity to EPA "may legitimately benefit from the confidential status of a specific chemical identity," and that "Congress could not have intended that such companies be forced to rely on another company to request to maintain the claim." JA130, 82 FR at 37,527.

Moreover, Congress specifically directed EPA "in carrying out" TSCA §8 to avoid reporting that is "unnecessary" to achieve the underlying statutory objectives and "minimize the cost of compliance" with rules issued under TSCA §8. 15 U.S.C. §2607(a)(5)(A)-(B); *see* JA164, 166, 169, EPA Response to Comments 31, 33, 36. EPA thus reasonably considered the difficulty of documenting and unpacking a history of corporate transactions over the past four decades merely to decide which entity may maintain an existing claim. *See* JA130, 82 FR at 37,527 (initial claimant may no longer exist); JA076, AFPM Comments 8 (businesses are acquired, merged, or leave the

marketplace); JA039, API Comments 4 (same); JA051, Specialty Graphic Imaging Ass'n Comments at 1 (initial claimant may no longer exist or may choose not to report); JA117, Pine Chems. Ass'n Int'l Comments 7 (acquiring company might not have manufactured chemical during applicable reporting period). Indeed, this is compounded by the fact that record-keeping requirements generally do not reach farther back than five to 10 years. *See* JA137, 82 FR at 37,534 (acknowledging varying corporate record retention policies); JA084-85, Am. Coatings Ass'n Comments 2-3 (same).

Ultimately, what Petitioner ignores is that under the regime adopted by EPA here, there will be a substantive review of any confidentiality claim that is maintained under the Reset Rule. There is thus no reason to artificially limit who may assert such claims or force EPA to engage in an administratively burdensome exercise of documenting what subsequent or successor manufacturer is in sufficient privity with the initial manufacturer that it may "maintain" the original claim. Under the Review Plan, EPA will assess all the confidentiality claims for chemical identity that are asserted under the Reset Rule and reject any that are not well founded, as directed by Congress in §8(b) of TSCA, 15 U.S.C. §2607(b).

Third, Petitioner posits that EPA could have simply directed manufacturers and processors that were not the initial claimant or its successor to assert a new confidentiality claim under TSCA §14. Pet. Br. 42-43 (citing 15 U.S.C. §2613(g)(1)(A)). In so arguing, Petitioner effectively acknowledges that manufacturers

that were not the initial claimants can have legitimate confidentiality claims. Further, nothing in TSCA contemplates that EPA would review *any* claims related to *existing chemicals* under the 90-day review process for new claims under TSCA §14. Rather, Congress directed EPA to review "*all claims* to protect the specific chemical identities of chemical substances on the confidential portion" of the Inventory under the Review Plan. 15 U.S.C. §2607(b)(4)(C) (emphasis added). In the Review Plan, "at a time required by the Administrator," EPA will set a deadline for claimants to substantiate "all claims" maintained in the Reset Rule, and will then complete its review within "5 years after" completing its reset. 15 U.S.C. §2607(b)(4)(D)(i) and (b)(4)(E). Congress further recognized that five years may not be enough and allowed EPA to extend the deadline two years. 15 U.S.C. §2607(b)(4)(E)(ii)(I) ("based on the number of claims" and "the available resources").

Petitioner's argument is not only unsupported, it is completely unworkable. *See e.g.*, *Adams v. SEC*, 287 F.3d 183, 191 (D.C. Cir. 2002) (rejecting interpretation that would "result in an unworkable rule"). The confidential portion of the Inventory lists approximately 18,000 chemical identities.[19] For claimants to document and EPA to adjudicate even a small portion of these complex claims in 90 days would be impossible. *See e.g.,* JA035, ACC Input on Proposed Rule at 2 (Nov. 18, 2016) (noting

[19] *See* Non-Confidential TSCA Inventory data file, https://www.epa.gov/tsca-inventory/how-access-tsca-inventory (last updated Apr. 19, 2018).

"scale of effort, and burden, on both industry and the agency" if EPA were to simultaneously conduct reset and the CBI review). Moreover, Congress did not intend for EPA to rush through the process of assessing thousands of highly-sensitive confidentiality claims over complex chemical identities in 90 days. That is why it gave EPA five to seven years to complete its review of existing claims, and only then to require expedited review of a relatively modest number of new claims.

Petitioner's interpretation would cause immediate harm to industry—with ripple effects across the economy. For decades, industry stakeholders have followed the premanufacture notice/*bona fide* notice of intent process required by EPA. Manufacturers and processors have reasonably relied on that confidentiality process to protect highly confidential trade secrets regarding chemical identities.[20] They have created important value in their products and businesses by being able to bring to market—but protect—these specific chemical identities, including information that the Reset Rule requires them to attest under penalty of perjury contains confidential business information. *E.g.*, 40 C.F.R. §710.37(e) (authorized official must certify claims for confidentiality "sought to be maintained … are true and correct" subject to 18 U.S.C. §1001). If EPA were to release that most sensitive of information, it would disrupt operations across the country, interfere with ongoing contractual relationships, and be "likely to cause substantial harm to the competitive position" of the

[20] *See* Morrison Testimony, *supra* at 10; ACC Response, *supra* at 2.

designating company. 40 C.F.R. §710.37(e)(3).[21] Had Congress intended for some reason to disrupt these long-settled expectations, it would surely have done so expressly, not in the opaque way Petitioner's reading requires.

II. EPA has permissibly interpreted TSCA §8 and TSCA §14 to require the proper substantiation and associated procedures in the Reset Rule.

Petitioner contends EPA did not properly include certain substantive and procedural requirements from TSCA §14 in the Reset Rule under TSCA §8. As an initial matter, Petitioner has no standing to bring these challenges. In any event, Petitioner is mistaken and blurs the requirements for *new* claims with TSCA's direction for *existing* claims. EPA's reading of the two provisions is entirely permissible.

TSCA sets forth a straightforward process for substantiating an existing confidentiality claim. *See* 15 U.S.C. §2607(b)(4)(B) (maintain claim); §2607(b)(4)(B)(iii), (b)(4)(D)(i) (substantiate claim, early or by EPA deadline in Review Plan); §2607(b)(4)(D)(ii) (substantiate under Review Plan). EPA followed this framework in the Reset Rule. It created a process for any manufacturer or processor to submit an existing claim, 40 C.F.R. §710.37(a), and defined what initial substantiation a claimant would need to submit, should it choose to substantiate a claim early, 40 C.F.R. §710.37(a)(1), (c). This early substantiation process includes

[21] The immediate release of CBI that Petitioner seeks would interfere with a company's ability to defend its intellectual property, a right Congress has sought to protect. *E.g.,* 18 U.S.C. §1836 (Defend Trade Secrets Act provides federal cause of action for misappropriation).

answering six "substantiation questions" under penalty of perjury, 40 C.F.R. §710.37(c)(1)(i)-(vi), (c)(2), and (e),[22] and certifying to four "statements," designed to ensure a confidentiality claim is legitimate. 40 C.F.R. §710.37(e).[23]

Given the substantial number of existing claims, EPA's approach reflects a reasonable reading of TSCA, as it encourages claimants to begin the review process for confidentiality claims over existing chemical identities sooner and allows EPA more time to evaluate any claims. Moreover, EPA specified reasonable requirements for early substantiation that draw from Congress' direction in both TSCA §§8 and 14. *See* 40 C.F.R. §710.37(c).

A. EPA's decision to require certification that confidential information is not readily discoverable through "reverse engineering" is reasonable.

Although Petitioner paints with a broad brush, its only direct challenge is to EPA's early substantiation procedure. Petitioner alleges (at 44-47) EPA should have expressly required a claimant to substantiate that a confidential chemical identity is not

[22] EPA has mandated that a claimant answer certain "substantiation questions." 40 C.F.R. §710.37(c)(1)(i)-(vi). The "substantiation questions" include asking the submitter to substantiate harm to their competitive position, identify precautions taken to protect confidential information, and address whether the information has been made public. *Id.*

[23] The certifications EPA required track the statutory requirements in TSCA §14(c)(1)(B), 15 U.S.C. §2613(c)(1)(B). An authorized official must certify (1) the company has taken reasonable measures to protect the information, and that the official (2) has determined that the information is not required to be disclosed, (3) has a reasonable basis to conclude disclosure would cause substantial competitive harm, and (4) has a reasonable basis to believe that the information is not readily discoverable through reverse engineering. 40 C.F.R. §710.37(e).

readily discoverable through "reverse engineering." Petitioner insists TSCA requires this, because, it reasons, TSCA §14 purportedly requires a claimant to substantiate that its substance's chemical identity cannot be reverse engineered. Petitioner lacks standing to bring this claim, (EPA Br. 35), because it has not shown how including a reverse engineering early substantiation provision would result in a different decision sufficient to cause Petitioner injury.

Regardless, on the merits, Petitioner's argument fails, as EPA has permissibly read TSCA §§8 and 14 to fashion reasonable substantiation requirements.[24] Specifically, following Congress' direction, EPA's early substantiation requirements in the Reset Rule drew directly from TSCA §14(c)(1)(B) which includes a statement that the person asserting confidentiality has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. §2613(c)(1)(B). The relevant early substantiation provision in the Reset Rule is identical. 40 C.F.R. §710.37(e)(4) ("I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering"). As EPA explained, such a certification ensures EPA receives valid and accurate information. JA140, 82 FR at 37,537.

[24] Petitioner also argues (at 48) that EPA changed its "substantiation questions" from its proposed rule without adequate notice. This claim too is meritless, as EPA proposed these questions, received comments, and explained the changes it made in the final Reset Rule in response to those comments. EPA Br. 37-38.

Nonetheless, Petitioner asserts (at 45) certification is not enough; TSCA allegedly requires "some" additional substantiation. Yet, nothing in TSCA §8 requires more. Rather, in TSCA §8, Congress delegated to EPA the discretion to determine what substantiation to require "pursuant to" TSCA §14 "and in accordance with" the Review Plan. 15 U.S.C. §2607(b)(4)(B)(ii) and (C). Likewise, TSCA §8(b)(4)(B)(i) directs EPA to maintain the Inventory "consistent with" TSCA §8 and §14, not "subject to" §14. 15 U.S.C. §2607(b)(4)(B)(i). TSCA, thus, did not require EPA in determining the treatment of existing confidentiality claims under TSCA §8 to apply every aspect of the "substantiation requirements" in TSCA §14(c)(3), which only apply to persons who submit new confidentiality claims "under" TSCA §14. 15 U.S.C. §2613(c)(3). TSCA instead offers a wide berth to EPA to determine what substantiation it may require for existing claims.

In all events, TSCA §14 does not specify that a "reverse engineering" statement must be "substantiated" in the way Petitioner alleges. TSCA §14(c)(1)(B)(iv) merely requires that the "assertion" of a confidentiality claim include a "statement" that there is no basis to believe the info is not readily discoverable through reverse engineering. 15 U.S.C. §2613(c)(1)(B)(iv). This is exactly what EPA did, and nothing in TSCA mandated EPA to do more. Rather, in TSCA §14(c) Congress granted EPA the discretion to set the rules for substantiating confidentiality. 15 U.S.C. §2613(c)(1)(A) (a person shall submit information "in accordance with such rules … as the Administrator has promulgated or may promulgate"); 15 U.S.C. §2613(c)(3) (a person

"shall substantiate the claim[] in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section"). Congress, thus, did not compel EPA to require claimants of existing claims to substantiate each "statement."

Petitioner contorts the statute even further when asserting that because TSCA §14(c)(2) exempts certain information from substantiation, and TSCA §14(c)(3) recognizes that exemption, it must mean that every other assertion not identified for exemption in TSCA §14(c)(2) in support of a claim must be substantiated. Pet. Br. 46-47 (citing 15 U.S.C. §2613(c)(2), (c)(3)). It is correct that TSCA §14(c)(2) does affirmatively preclude EPA from requiring a claimant to substantiate certain kinds of information. 15 U.S.C. §2613(c)(2) ("the following information shall not be subject to substantiation requirements"). However, that does not mean that the converse must be true—that in establishing rules to substantiate a claim, EPA must require a claimant to substantiate everything that is not in TSCA §14(c)(2). That is particularly true given that Congress specifically provided that a manufacturer must make a "statement" regarding "reverse engineering," but did not specifically require additional "substantiation" with regard to "reverse engineering."

At a minimum, EPA's reading of the statute is entirely permissible. EPA explained that it would include the four specific "statements" in TSCA §14(c)(1)(B) in the Reset Rule's certification provisions to gather this information where earlier assertions in support of existing claims may have predated the current provisions in TSCA §14(c). JA140, 82 FR at 37,537. EPA also explained that certification

statements are consistent with past agency practice and serve to put the submitter on notice of the consequences of submitting false information to the agency. *Id.* Petitioner simply asserts without proof or citation to the record that express statements certified as true and correct are insufficient to ensure there is a foundation for the confidentiality assertion—particularly given EPA would be subsequently reviewing the claim and would be able to evaluate whether a certification was not well-founded. *See also* 18 U.S.C. §1001 (crime for false statements). EPA took reasonable action to achieve Congress' intent as directed under the statute.

B. The Reset Rule properly establishes procedures for considering substantiation of requests to maintain existing claims.

Petitioner again broadly asserts (at 49-52) that EPA failed to require in the Reset Rule review of certain confidentiality claims within 90 days. Petitioner again misses the mark.

As a preliminary matter, Petitioner lacks standing to raise this claim because "[i]t is seeking to enforce a statutory deadline provision that by its terms does not require public disclosure of information." *Friends of Animals v. Jewell*, 828 F.3d 989, 992 (D.C. Cir. 2016); *see also* EPA Br. 41. With regard to this aspect of TSCA §14, Petitioner "is not entitled to any information." 828 F.3d at 990. Here, as in *Jewell*, "[t]he disclosure requirement [Petitioner] points to as the source of its informational injury does not impose any obligations on [EPA] until a later time." 828 F.3d at 992. TSCA §14 requires EPA to review and decide upon certain claims within 90 days of

receipt of such claim. 15 U.S.C. §2613(g)(1). *After* making a decision, EPA must notify the claimant of a negative decision and allow the claimant the opportunity to appeal the decision in federal district court. 15 U.S.C. §2613(g)(2). *After* a court rules for disclosure, subject to any appeal, EPA would make the information publicly available. 15 U.S.C. §2613(b)(5). Petitioner thus lacks standing to raise this claim. EPA Br. 40-41.

Even if Petitioner had standing, its claims fail on the merits, as EPA reasonably followed Congress' direction in TSCA §8 with respect to how it will evaluate requests to maintain existing confidentiality claims for chemical identities, and its treatment of other confidentiality claims does not conflict with Congress' direction in TSCA §14.

TSCA §8 governs existing claims, and directs EPA to set any deadlines for reviewing existing confidentiality claims for chemical identities in its future Review Plan. 15 U.S.C. §2607(b)(4)(B) (Reset Rule); *id.* at (C)-(D) (Review Plan). Petitioner concedes this clear statutory direction. Pet. Br. 50, n.6. Petitioner nonetheless argues that under TSCA §8(b)(5)(B)(i) and §14(g)(1), 15 U.S.C. §§2607(b)(5)(B)(i), 2613(g)(1), EPA must review the redesignation of an existing confidential chemical from "inactive" to "active" within 90 days. Pet. Br. 50.

That reading completely misses the point of the Reset Rule. TSCA §8(b)(5)(B)(i)—captioned "In General"—is a general provision for *future* changes from inactive to active status. 15 U.S.C. §2607(b)(5)(B)(i). By contrast, TSCA §8(b)(4)(D) is specific to the chemical identities claimed through the Inventory reset,

"*all*" of which are to be evaluated under the future Review Plan. 15 U.S.C. §2607(b)(4)(C)(emphasis added). The specific statutory direction of the latter trumps the general language of the former. *See Mittleman v. Postal Regulatory Comm'n*, 757 F.3d 300, 306 (D.C. Cir. 2014).

With respect to information other than the chemical identity, the Reset Rule is wholly consistent with TSCA §14. EPA requires that such information be treated in accordance with EPA's existing general CBI regulations at 40 C.F.R. part 2. 40 C.F.R. §710.37(b). Petitioner argues that somehow these regulations prevent EPA from complying with TSCA §14, Pet. Br. 49-52, but failed to raise this in its comments. *See* JA110, EDF Comments 17 (general comment that EPA should "make clear" that TSCA §14 applies to CBI claims, but no mention of alleged incompatibility of EPA CBI regulations). An objection to a proposed rule must be raised with "reasonable specificity" during the public comment period to be raised during judicial review. *Nat. Res. Def. Council v. EPA*, 571 F.3d 1245, 1259-60 (D.C. Cir. 2009) (petitioner did not provide EPA adequate notice of its objection to suspension of contingency measures when it commented on EPA's general suspension authority). Petitioner's comment was insufficient to put EPA on notice that it objected to EPA's use of its CBI regulations, and Petitioner has thus waived this argument before the Court. Regardless, these regulations do not contradict the requirements of TSCA §14, and beyond conclusory statements, Petitioner fails to support its claims. *See* EPA Br. 42-44.

III. EPA reasonably did not address in the Reset Rule when and how it would make available to the public the "unique identifier" information under TSCA §8(b)(7).

Petitioner asserts EPA has "completely failed to implement" in the Reset Rule TSCA's requirement to make publicly available "unique identifiers" for confidential chemicals. Pet. Br. 52-54 (citing TSCA §8(b)(7), 15 U.S.C. §2607(b)(7)). As an initial matter, Petitioner's challenge is not ripe, because EPA has not taken final action under the Reset Rule on when and how the agency will make unique identifiers publicly available. This Court has stated that it will not undertake review requiring it to "'conduct a pseudo-rulemaking proceeding' by examining and weighing all of the considerations that might lead" the agency to pursue a certain course of action. *Munsell v. Dep't of Agric.*, 509 F.3d 572, 585-87 (D.C. Cir. 2007) (citation omitted). Judicial review is not on "surer footing" when "it is unclear ... when or how the agency will employ" the challenged provision. *City of Houston, Tex. v. HUD*, 24 F.3d 1421, 1430-31 (D.C. Cir. 1994) (citations omitted).

EPA did not assign unique identifiers now because it only makes sense to do so after EPA completes other scheduled regulatory proceedings. Separate from the Reset Rule, Congress directed EPA to "make available to the public…the unique identifier assigned" by EPA "*under* [TSCA §14]" for each chemical on the confidential portion of the Inventory. 15 U.S.C. §2607(b)(7)(B). Under TSCA §14, EPA will "develop a system to assign a unique identifier to each specific chemical identity *for which the Administrator approves* a request for protection from disclosure." 15 U.S.C.

§2613(g)(4)(A)(i) (emphasis added). Yet, EPA would only "approve" a request *after* it completes its reviews of existing confidentiality claims over chemical identities in EPA's future Review Plan. 15 U.S.C. §2607(b)(4)(C) (providing for review for "all" claims in plan to be proposed one year after the Inventory is reset). In short, how EPA will assign unique identifiers to confidential chemicals and make them available to the public rests on decisions that EPA has not yet made under a process that does not yet exist. Until EPA acts on this issue, Petitioner's claim is not ripe.

To the extent Petitioner is arguing TSCA required EPA to have affirmatively stated its intention now under the Reset Rule as to how it will assign unique identifiers and that it will publish the unique identifiers in the first published Inventory after EPA completes the reset, that argument also fails. Nothing in TSCA requires that as part of the Reset Rule.

On the contrary, as outlined, TSCA provided a stepwise process for EPA to follow before it can address the unique identifier requirement—first collect information to reset the Inventory in the Reset Rule, then promulgate the Review Plan to decide confidentiality claims, and then implement a system to assign a unique identifier. 15 U.S.C. §2607(b)(4)(A)-(E), §2613(g)(4). Moreover, TSCA §8(b)(7) does not require that EPA address public information requirements in the Reset Rule. It simply provides that EPA "shall make available to the public" certain information, with no direction that EPA must do so in the Reset Rule. 15 U.S.C. §2607(b)(7). EPA has "significant latitude as to the manner, *timing*, content and coordination of its

regulations." *WildEarth Guardians v. EPA*, 751 F.3d 649, 654 (D.C. Cir. 2014) (emphasis in original). EPA has reasonably applied that latitude here. *See* JA135, 82 FR at 37,532 (TSCA §8(b)(7) gives EPA discretion on manner and timing of fulfilling public information requirements).

EPA acknowledged that it must comply with the obligations imposed by TSCA §8(b)(7) and explained that it intended to do so. *See* JA135-36, *Id.* at 37,532-33 ("TSCA section 8(b)(7) requires EPA to make active and inactive designations available to the public."). EPA had already begun doing so.[25] Petitioner not only fails to acknowledge these developments, it also cannot identify a single statement in the final rule or preamble indicating that EPA does not intend to make available to the public the information required by TSCA §8(b)(7). Hence, Petitioner's claim that EPA did not decide now whether it "would" implement the unique identifier requirement is baseless.

IV. EPA reasonably exempted export-only chemicals from the Reset Rule.

EPA's decision to exempt export-only chemicals from the notification process of the Reset Rule is reasonable and permissible.[26] Petitioner argues (at 55-56) that

[25] *See* 87 FR 23186 (May 8, 2017) (soliciting comments on alternatives for unique identifier); 83 FR 5623 (Feb. 8, 2018) (same).

[26] Petitioner erroneously contends (at 57) that EPA failed to provide adequate notice that export-only chemicals would not be covered by the Reset Rule notification process. EPA in fact teed this issue up in its notice and received several comments on exactly this point, so this argument is without merit. EPA Br. 50-51 (discussing proposal and comments).

EPA "contradicts" TSCA §12 by exempting export-only chemicals from the Reset Rule notification process under 40 C.F.R. §710.27(a)(4). This misses the mark, as Congress did not require EPA to include export-only chemicals in the Inventory reset, and EPA reasonably exercised its discretion to interpret TSCA to exclude them.

EPA's discretion to exclude export-only chemicals is clear. In the Amendments, Congress directed "the Administrator, by rule," to create a process for manufacturers and processors to notify EPA regarding chemicals that were already "on the [Inventory]" and had been manufactured or processed in recent years "for a nonexempt commercial purpose." 15 U.S.C. §2607(b)(4)(A)(i). As Congress did not define the phrase "nonexempt commercial purpose," EPA has the discretion to determine what commercial purposes to exempt from the notification process. *Chevron U.S.A. v. NRDC,* 467 U.S. 837, 842-43 (1984).

In the Reset Rule, EPA reasonably exercised that discretion to interpret manufacturing "for a nonexempt commercial purpose" to exclude export-only chemicals based on the "limited nature of these commercial activities and the exemptions from PMN reporting." JA131, 82 FR at 37,528. Even prior to the Amendments, TSCA §12(a)(1)(A) exempted export-only chemicals from the TSCA §5 premanufacture notice process. 15 U.S.C. §2611(a)(1)(A) ("this chapter," including TSCA §5, "shall not apply" to export only chemicals). Thus, EPA's regulations have expressly excluded export-only chemicals from premanufacture notice requirements. 40 C.F.R. §720.30(e) (chemicals that are "not subject to the [premanufacture]

notification requirements" include "[a]ny new chemical substance manufactured solely for export").

In light of TSCA's exclusion of export-only chemicals from the premanufacture notice process, EPA's treatment of these chemicals in the Reset Rule was sound. As described *supra,* a manufacturer follows the TSCA §5 premanufacture notice process in order to manufacture a chemical for use in the United States. 15 U.S.C. §2604. Hence, the premanufacture notice process is the principal way in which chemicals are included on the Inventory. *See* 15 U.S.C. §2607(b)(1) (Inventory "shall at least include each chemical substance which any person reports" under TSCA §5). As premanufacture notices are not required for export-only chemicals, and few chemicals for export were placed on the Inventory,[27] EPA reasonably excluded them.

Moreover, EPA's approach avoids creating an illogical distinction between current and future export-only chemicals. *Util. Air Regulatory Grp. v. EPA*, 134 S. Ct. 2427, 2442 (2014) (rejecting interpretation inconsistent with "structure and design" of the overall statute). The Amendments do not change the exemption for export-only chemicals from the TSCA §5 premanufacture notice process. *See* Amendments, Pub. L. 114-182, Title I, §10 (no changes to 15 U.S.C. §2611(a)(1)). Thus, because the TSCA §5 premanufacture notice process is the principal avenue for adding a chemical

[27] Although not required, some manufacturers may have voluntarily added an export-only chemical to the Inventory. EPA Br. 48-49.

to the Inventory, and because TSCA §12 continues to exempt export-only chemicals from that process, a new chemical manufactured or processed solely for export after the Inventory is reset would not be required to be added to the Inventory. It simply makes no sense to read TSCA §8(b)(4)(A)(i) as requiring manufacturers to provide "notice" of export-only chemicals when TSCA otherwise exempts new chemicals from the §5 premanufacture notice process and that is unchanged by the Amendments.

Further, EPA reasonably placed a limit on its exclusion. The Reset Rule provides that export-only chemicals would nonetheless trigger notification requirements "where the Administrator has made a finding described in TSCA section 12(a)(2)." 40 C.F.R. §710.27(a)(4). A TSCA §12(a)(2) finding is made where "the Administrator finds" a chemical "presents an unreasonable risk of injury to health within the United States or to the environment of the United States." 15 U.S.C. §2611(a)(2). Hence, where there are compelling public health reasons to impose notifications requirements on an export-only chemical, EPA will do so.

Petitioner nonetheless argues (at 56-57) that TSCA prohibits EPA from excluding "export-only chemicals." According to Petitioner, "specific" language in TSCA §12 that exempts exports from TSCA provisions "other than" TSCA §8, governs the "general" language establishing the Inventory in TSCA §8. Petitioner has it backwards. Here, the specific language is in TSCA §8 and the general language is in TSCA §12. TSCA §8(b)(4)(A)(i) includes specific direction to EPA on what it must

include in the Reset Rule, and expressly required, by a specific date, that the "Administrator, by rule," determine exempt commercial purposes. 15 U.S.C. §2607(b)(4)(A)(i) (no "later than 1 year after June 22, 2016, *the Administrator, by rule, shall*" require notice "of each chemical substance … that the manufacturer or processor … has manufactured or processed for a *nonexempt commercial* purpose" (emphases added)). TSCA §12(a), by contrast, applies to TSCA generally. 15 U.S.C. §2611(a) (addressing exports "In general"). Hence, consistent with the overall structure of TSCA, EPA properly interpreted the specific language of TSCA §8(b) to define the scope of the Inventory.

V. If the Court Rules Against EPA, the Court Should Remand without Vacatur.

As the foregoing demonstrates, EPA's action is well-supported by the statute and is reasonable. If, however, the Court finds that EPA has not adequately explained itself or that the record is somehow insufficient to support EPA's conclusions, the proper remedy is remand to the agency for further proceedings. Petitioner's request for vacatur of 40 C.F.R. §710.37 (Reset Rule process for requests to maintain existing claims) and 40 C.F.R. §710.27(a)(4) (its export-only exemption) should be denied.[28]

[28] Additionally, Petitioner requests (at 58) the Court vacate portions of the Reset Rule preamble discussing EPA's rationale in promulgating these provisions. Because the preamble is not the agency's decision, it is not subject to vacatur, and the Court should deny this request. *See Wyo. Outdoor Council v. U.S. Forest Serv.*, 165 F.3d 43, 53 (D.C. Cir. 1999) (preamble is not operative part of a regulation).

As this Court explained in *Allied-Signal v. U.S. Nuclear Regulatory Comm'n*, 988 F.2d 146, 151 (D.C. Cir. 1993), remand is preferable where an agency could readily provide a better explanation for its decision if so directed. *See also Cty. of Los Angeles v. Shalala*, 192 F.3d 1005, 1023 (D.C. Cir. 1999) (for additional explanation, proper course is remand "except in rare circumstances"); *Milk Train, Inc. v. Veneman*, 310 F.3d 747, 756-57 (D.C. Cir. 2002) (where "there is at least a serious possibility" the agency could on remand explain its decision, that factor "favors remanding rather than vacating" (citation omitted)). Here, as explained above, EPA's actions in the Reset Rule are, at a minimum, well within its authority.

Remand is also favored where, as here, vacating the rule would be extremely disruptive. *Allied-Signal*, 988 F.2d at 151. Congress directed EPA to require that manufacturers submit notifications within 180 days of the Reset Rule's publication—*i.e.*, by February 7, 2018. 15 U.S.C. §2607(b)(4)(A)(i). Congress clearly intended for EPA to quickly reset the Inventory, so the agency could move ahead with other requirements in the Amendments that depend upon the revised Inventory.

Further, remand is appropriate where an agency would be unable to address the consequences of a vacatur in a later-adopted rule. *Allied-Signal*, 988 F.2d at 151. Here, Petitioner's request—that the Court vacate the process for requesting to maintain an existing claim and order EPA to conduct a new rulemaking to require non-original claimants and their successors in interest to withdraw their requests—could result in EPA disclosing confidential active chemical identities, 15 U.S.C. §2607(b)(4)(B)(iii),

leaving thousands of manufacturers and processors at risk of losing the protection of their confidential information without an opportunity to defend their rights on the merits. Once the chemical identities are publicly disclosed, EPA cannot "un-disclose" them, and the confidentiality would be lost, regardless of any later-promulgated rule. EPA, and a court, could not "unring the bell." *Maness v. Meyers*, 419 U.S. 449, 460 (1975).

CONCLUSION

The petition should be denied.

Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the typeface requirements of Fed. R. App. P. 32(a)(5) and type-style requirements of Fed. R. App. P. 32(a)(6) because it has been prepared in a proportionally spaced typeface using Microsoft Word in 14-point Garamond font.

This brief complies with the word-count limitation of Fed. R. App. P. 32(e). This brief contains 9,048 words, not counting the parts excluded by Fed. R. App. P. 32(f) and Circuit Rule 32(e)(1).

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CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2018, I will cause the foregoing document to be electronically filed through this Court's CM/ECF system. Participants in the case who are registered CM/ECF users will be served by the CM/ECF system.

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