[NOT YET SCHEDULED FOR ORAL ARGUMENT]

No. 23-1166 & 1204

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

ENVIRONMENTAL DEFENSE FUND,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

AMERICAN CHEMISTRY COUNCIL, ET AL.,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

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

BRIEF OF RESPONDENT EPA

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties and Amici.

All parties and intervenors are identified in EDF's and ACC's briefs.

B. Rulings Under Review.

Petitioners seek review of the final rule of the U.S. Environmental Protection Agency, entitled "Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)," which is published at 88 Fed. Reg. 37155 (June 7, 2023).

C. Related Cases.

Case Nos. No. 23-1166 & 1204 are related.

s/ Phillip R. Dupré
PHILLIP R. DUPRÉ

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GLOSSARY

ACC – American Chemistry Council

APA – Administrative Procedure Act

CAS – Chemical Abstract Services

CAS RN® – Chemical Abstract Services Registry Number

CBI – Confidential Business Information

EDF – Environmental Defense Fund

EPA – Environmental Protection Agency

FOIA – Freedom of Information Act

TSCA – Toxic Substances Control Act

INTRODUCTION

This case concerns the U.S. Environmental Protection Agency's ("EPA" or "Agency") rulemaking regarding treatment of confidential business information (CBI) claims under the Toxic Substances Control Act ("TSCA"). Two petitions challenge discrete portions of the rule. Petitioner Environmental Defense Fund ("EDF") argues that some provisions are too protective of information submitted under TSCA and claimed as CBI. Petitioners American Chemistry Council and American Fuel and Petrochemical Manufacturers (collectively "ACC") argue that one provision of the rule is not protective enough of such information. Neither is correct. EPA's approach provides appropriate protection for information submitted under TSCA in compliance with Congress's statutory commands. EPA used the rulemaking authority delegated by Congress to strike an appropriate balance between disclosure and protection consistent with the statute. Both petitions for review should be denied.

STATEMENT OF JURISDICTION

Petitioner EDF and Petitioner ACC challenge EPA's final rule, entitled Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 37155 (June 7, 2023), hereinafter the "CBI Rule." This Court has jurisdiction to review EDF's and ACC's challenges pursuant to TSCA § 19(a)(1)(A), 15 U.S.C. § 2618(a)(1)(A).

PERTINENT STATUTES AND REGULATIONS

All applicable statutes and regulations are contained in Petitioner EDF's and Petitioner ACC's Principal Briefs.

STATEMENT OF THE ISSUES

1. TSCA does not allow for confidentiality of most information contained in a health and safety study. Did EPA reasonably exclude from the regulatory definition of "health and safety study" information that does not pertain to the effect of a chemical substance or mixture on health, the environment, or both, such that the excluded information is potentially eligible for confidential treatment?

2. Where TSCA exempts certain CBI claims from substantiation and review requirements when they are asserted prior to the chemical's commercialization, whether such CBI claims lose this exemption, and become subject to retroactive substantiation and review requirements, if and when the chemicals are later commercialized.

3. Whether EPA reasonably decided to withhold its judgment regarding final confidentiality determinations of CBI claims with identified deficiencies until the end of the statutory review period and whether EPA reasonably recognized that

TSCA permits, rather than requires, public disclosure of all information determined not to be entitled to confidential treatment.[1]

4. Where TSCA and longstanding EPA policy have provided that chemical identity CBI claims are waived where chemical identity information is later submitted without a confidentiality claim, whether EPA reasonably determined that concerns about potential waiver of CBI claims created from reporting by companies that may lack knowledge of the specific chemical identity and report using non-confidential identifiers, such as accession numbers, for certain chemicals are best addressed in specific reporting rules, as opposed to the CBI Rule.

STATEMENT OF THE CASE

A. Statutory Background

Congress enacted TSCA to prevent unreasonable risks to health and the environment associated with the manufacture, processing, distribution in commerce, use and disposal of certain chemical substances and mixtures. *See* 15 U.S.C. §§ 2601-97. TSCA was designed to enable review and potential regulation of such chemicals prior to their manufacture, processing, distribution in commerce, and use and disposal, rather than only after exposure to them has already occurred.

[1] Other statutes, such as the Privacy Act, 5 U.S.C. § 552a, may impose restrictions on disclosure of certain information not entitled to confidential treatment under TSCA's provisions in 15 U.S.C. § 2613.

S. Rep. No. 94-698, at 5 (1976), reprinted in Legislative History of TSCA at 161; H.R. Rep. No. 94-1341, at 1, 6 (1976), reprinted in Legislative History of TSCA at 409, 414 (Comm. Print 1976). In particular, TSCA provides EPA authority to require reporting, record-keeping, and testing, and to impose restrictions relating to chemical substances and mixtures.

In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "2016 Amendments"), which amended TSCA. Pub. L. No. 114-182, 130 Stat. 448 (2016). The 2016 Amendments changed TSCA in a number of substantive ways, including substantial revisions to the assertion and treatment of CBI under 15 U.S.C. § 2613.[2] As discussed *infra*, the 2016 Amendments *inter alia* imposed new statutory requirements for the assertion of CBI claims, provided that certain information is ineligible for confidential treatment, insulated other types of information from routine review of confidentiality claims, expanded disclosure requirements to certain entities, and set requirements and deadlines for routine CBI claim review.

In making these widespread changes, Congress sought to

> [strike] a balance between protecting trade secrets and sensitive commercial and financial information and broadening access to information[,] [which is] essential to . . . encourage innovation and economic competitiveness within the chemical industry and those industries that use chemistry, while better

[2] Although the Petitioner briefs and other documents quoted in this brief refer to Section 14 of TSCA, in citations we use the U.S. Code sections for clarity.

> informing the decisions made about chemicals by different levels of government, companies throughout the supply chain, and the general public.

S. Rep. No. 114-67, at 21 (2015).

EPA administers 15 U.S.C. § 2613, and TSCA in general, in a manner intended to implement the balance sought by Congress.

1. TSCA Inventory of Chemical Substances (Section 8(b), 15 U.S.C. § 2607(b))

Section 8(b) of TSCA, 15 U.S.C. § 2607(b), requires EPA to compile, keep current, and publish an inventory of chemical substances manufactured or processed in the United States. This Inventory was developed shortly after TSCA was first enacted, and lists all chemical substances that have been manufactured, processed, or imported in the United States except for those that (1) were excluded from the original Inventory reporting requirements or (2) qualify for an exemption or exclusion from new chemical reporting and review under TSCA Section 5(a)(1), 15 U.S.C. § 2604(a)(1). The Inventory thus includes chemical substances identified during the creation of the Inventory, *see* 15 U.S.C. § 2607(b), and each chemical substance for which a Premanufacture Notice (commonly referred to as a "PMN") has been submitted[3] and manufacture has commenced, as of the date such substance is manufactured in the United States. 15 U.S.C. § 2607(b)(1).

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[3] Under TSCA Section 5, 15 U.S.C. § 2604 and 40 C.F.R. part 720, a person intending to manufacture or import a new chemical substance (defined as a

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To implement the TSCA Inventory in a manner that protects confidentiality while also assisting the public in ascertaining which chemical substances are already in commerce in the U.S., the Inventory has two distinct sections. The public portion of the Inventory includes: (1) nonconfidential chemical substances, identified by their specific chemical identities and a Chemical Abstracts Service Registry Number ("CAS RN®");[4] and (2) public identifiers for chemical substances whose identities are claimed as confidential: generic chemical names that do not release confidential information, and a unique, EPA-assigned nonconfidential "Accession Number" for that individual substance. The confidential portion of the Inventory, which is maintained by EPA but not available to the public, includes specific chemical names for chemical substances claimed as confidential (it may also include other specific identifiers such as CAS RN®s). These chemical substances are listed in the public portion of the Inventory by a TSCA Accession Number and a generic chemical name that masks the specific substance identity. 40 C.F.R. § 720.25(b)(1); *see also* 15 U.S.C. § 2607(b)(7)(B).

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chemical substance not on the Inventory, 15 U.S.C. § 2602(11)) must submit a Premanufacture Notice to EPA. EPA must review the notice to make a determination regarding the likelihood that the new chemical substance "presents an unreasonable risk of injury to health or the environment." 15 U.S.C. § 2604(a)(3)(A). If EPA allows manufacture of the substance and manufacture commences, the chemical substance is added to the Inventory.

[4] Thus, if a CAS RN® relating to a confidential chemical identity is disclosed to the public, that in turn discloses the confidential chemical identity.

2. TSCA Confidential Business Information (Section 14, 15 U.S.C. § 2613)

Section 14 of TSCA, 15 U.S.C. § 2613, identifies specific information submitted under TSCA that EPA must protect from disclosure to protect certain sensitive commercial and financial information commonly referred to as CBI.[5] *See* 15 U.S.C. § 2613. The primary prohibition on disclosure is in 15 U.S.C. § 2613(a), which requires that EPA protect from disclosure information that meets the requirements of that section and Exemption 4 of the Freedom of Information Act (FOIA), 5 U.S.C. § 552(b)(4), i.e., ‘‘trade secrets and commercial or financial information obtained from a person and privileged or confidential.’’ Subject to specific, narrow disclosure authority found in 15 U.S.C. § 2613(d), EPA may not disclose such information until the Agency has made a formal determination of eligibility for confidential treatment and followed statutorily required procedures. 15 U.S.C. § 2613(g). EPA confidentiality regulations at 40 C.F.R. part 2, subpart B, and part 703 provide that such CBI must be treated in accordance with those regulations and with 15 U.S.C. § 2613. Where certain information is to be

[5] The rule at issue here concerns “the assertion and treatment of [CBI] claims for information reported to or otherwise obtained by EPA under [TSCA].” 88 Fed. Reg. at 37155. Thus, unless otherwise specified, references to “CBI” in this brief mean information subject to a claim of business confidentiality by the submitter. EPA confidentiality regulations at 40 C.F.R. part 2, subpart B, and part 703 provide that such CBI must be treated in accordance with those regulations and with 15 U.S.C. § 2613.

disclosed, the statute provides procedures designed to protect the submitter's rights. *See* 15 U.S.C. § 2613(g)(2).

15 U.S.C. § 2613 contains no language *requiring* disclosure of information solely because it has been determined not to be entitled to confidential treatment after a review conducted under Section 2613(g). It does, however, contain provisions requiring limited mandatory disclosures related to protecting health or the environment. *See* 15 U.S.C. § 2613(d). Additionally, as discussed *infra*, certain provisions elsewhere in TSCA mandate public disclosure of narrow categories of information, where Section 2613 protection does not apply.

TSCA authorizes EPA to promulgate rules regarding the assertion and treatment of confidentiality claims. 15 U.S.C. § 2613(c)(1)(A) ("A person seeking to protect from disclosure any information that person submits under this chapter . . . 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"); *see also* 15 U.S.C. § 2613(c)(3) (requiring that confidentiality claims be substantiated "in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section").

3. Assertion and Substantiation of Confidentiality Claims

15 U.S.C. § 2613 contains several requirements for the assertion and substantiation of CBI claims. Section 2613(c)(1)(A) requires that "[a] person seeking to protect from disclosure any information that person submits under [TSCA] 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). TSCA further requires that the claims be certified and substantiated. 15 U.S.C. § 2613(c)(1)(B), (c)(3), and (c)(5). "[A] person asserting a claim to protect information from disclosure . . . shall substantiate the claim." 15 U.S.C. § 2613(c)(3). EPA has interpreted this provision to require substantiation "at the time of submission to EPA." 40 C.F.R. § 703.5(b)(1). Certain categories of information are expressly exempt from the substantiation requirements. 15 U.S.C. § 2613(c)(2).

4. Confidentiality Claims for Chemical Identity

Chemical identity, though not defined in TSCA,[6] is a term used to capture the concept that each chemical or substance is distinct and can be uniquely described and identified. The term also refers to the specific chemical name[7] (such

[6] Nonetheless, TSCA uses the term "chemical identity" numerous times, both in 15 U.S.C. § 2613(c)(1)(C), and elsewhere, *e.g.*, 15 U.S.C. § 2607(a)(2)(A).

[7] EPA guidance explains that "[a] specific chemical name identifies every structural feature of a chemical substance possible." Guidance for Creating Generic

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as a Chemical Abstract Service ("CAS") name or a name according to any of several other structural naming conventions used in chemistry) or number (such as a CAS registration number)[8] and is used to uniquely identify a chemical substance. In the context of administering TSCA, EPA typically uses the term to refer to a specific chemical name (usually the CAS name), CAS RN® and/or TSCA Inventory accession number, and structural diagrams.

Although chemical identity is generally subject to substantiation requirements and CBI claim review, 15 U.S.C. § 2613(c)(2) carves out specific classes of information not subject to substantiation requirements.[9] Relevant here, Section 2613(c)(2)(G) carves out a limited exemption for CBI claims for chemical identity that are asserted prior to the date on which a chemical substance is first offered for commercial distribution:

Names for Confidential Chemical Substance Identity Reporting under the Toxic Substances Control Act, https://www.epa.gov/sites/default/files/2018-06/documents/san6814_guidance_for_creating_tsca_generic_names_2018-06-13_final.pdf.

[8] A Chemical Abstract Service Registration Number (CAS RN®) is a unique numerical identifier created by the Chemical Abstracts Service for chemical substances. *See, e.g.*, 40 C.F.R. § 720.25(b)(1). The CAS RN® links to a specific chemical identity.

[9] As discussed *infra*, the classes of CBI claims not subject to upfront substantiation requirements per 15 U.S.C. § 2613(c)(2) are likewise exempt from routine CBI claim review per §§ 2613(g)(1)(A) and 2613(g)(1)(C) (the latter referring specifically to CBI claims for the chemical identity of pre-commercialized chemical substances).

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

15 U.S.C. § 2613(c)(2).

Chemical identity is unique among CBI claims. Most other confidentiality claims pertain to the link between a submitter and specific information provided by that submitter (e.g., the fact that Company A produces Chemical X, a commonly known chemical). If Company A chooses not to claim CBI for its manufacture of Chemical X, that information would be publicly available even if other companies manufacture Chemical X and have claimed the fact of manufacture as confidential. Nonetheless, disclosure to the public of the fact that Company A is manufacturing Chemical X does not affect the CBI claims of the other companies that have claimed their own manufacture of Chemical X as confidential. By contrast, a CBI claim for the *identity* of Chemical X pertains to the fact that *anyone* is manufacturing Chemical X for commercial purposes in the United States. 42 Fed. Reg. 64572, 64574 (Dec. 23, 1977). Valid CBI claims for chemical identity

prohibit EPA from disclosing the chemical name of the substance.[10] EPA is required to mask the identity of the chemical such that no other entity (e.g., a competitor or a private citizen) can know the name of that chemical substance or its chemical structure. Conversely, denial of a CBI claim for chemical identity would allow disclosure of the chemical identity, although it would not result in the disclosure of other information regarding the chemical substance that might be claimed as CBI, e.g., the manufacturer or the amounts produced.

EPA has long taken the position that one submitter failing to assert a confidentiality claim for the identity of Chemical X could cause that chemical identity to lose its confidential status. *See* 50 Fed. Reg. 9944, 9950 (Mar. 12, 1985) ("If a manufacturer reports under this rule a chemical substance whose identity is held confidential on the inventory, and the manufacturer does not claim the chemical identity confidential, EPA will consider the identity of that substance no longer confidential for purposes of the Inventory because the fact that [some unidentified entity] is manufacturing or importing it for commercial purposes is not confidential."); 42 Fed. Reg. at 64591. This does not mean, however, that other information regarding the chemical substance that might still be claimed as CBI

[10] Assertion of a CBI claim whose validity has yet to be determined also requires that the underlying information be protected, pending that determination. 15 U.S.C. § 2613(g); 40 C.F.R. parts 2 and 703.

also loses protection from disclosure. Accordingly, the failure of even one entity manufacturing Chemical X to assert a CBI claim for the chemical identity of Chemical X means that the fact that Chemical X is manufactured for commercial purposes is no longer protected from disclosure under 15 U.S.C. § 2613.

5. Review of Confidentiality Claims

15 U.S.C. § 2613 also dictates when EPA may, may not, or even must review certain CBI claims; sets quotas for claim review; and specifies the timeframe for review of those claims subject to a quota.

TSCA mandates review of certain CBI claims, including claims for chemical identity, "[e]xcept for claims regarding information described in subsection (c)(2)." 15 U.S.C. § 2613(g)(1)(A). Section 2613(g)(1)(A) requires EPA to approve, approve in part and deny in part, or deny confidentiality claims. Section 2613(g)(1)(C) further specifies that Section 2613(g)(1)(A) review include all confidentiality claims for chemical identity "except with respect to information described in subsection [15 U.S.C. § 2613](c)(2)(G)" and a ''representative subset'' comprising at least 25% of all other claims. Confidentiality determinations under 15 U.S.C. § 2613(g)(1)(A) must be issued within 90 days of assertion of the CBI claim.

15 U.S.C. § 2613(f) establishes additional triggers for discretionary or mandatory substantiation and review of information that has previously been

claimed confidential. Relevant here, Section 2613(f)(2)(A) requires any person that has made a CBI claim in a submission to reassert and substantiate, or resubstantiate, that claim upon EPA's receipt of a request for that submission under the FOIA.

6. Health and Safety Studies

15 U.S.C. § 2613(b) includes several exemptions to the general prohibition on disclosure of CBI. Among them is Section 2613(b)(2), which provides that Section 2613(a) does not prohibit disclosure of certain health and safety studies and information from health and safety studies. TSCA defines a health and safety study as:

> "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter."

15 U.S.C. § 2602(8).

The health and safety study exemption itself has limits. It applies only to information regarding: (1) chemical substances or mixtures offered for commercial distribution by the date of disclosure; and (2) any chemical substances or mixtures for which testing is required under TSCA Section 2603 or for which notification is required under Section 2604. 15 U.S.C. § 2613(b)(2)(A). Additionally, the

exemption does not apply to information that discloses certain processing information or portions of a mixture. *Id*.

7. TSCA Reporting Rules

TSCA contains several provisions granting EPA authority to collect information in the administration of TSCA. EPA exercises such authority through rules commonly referred to as reporting rules. For example, 15 U.S.C. § 2607(a), provides EPA authority to require manufacturers and processors to report a great variety of information regarding chemical substances and mixtures including chemical identity and molecular structure, production volume, and categories of use. Section 2607(d), in turn, provides authority to require the submission of health and safety studies. And Section 2607(a)(7) requires reporting on PFAS manufactured since January 1, 2011. All these provisions are implemented via rules that specify, among other things, who is required to submit reports and what information must be reported. *See* 88 Fed. Reg. 70516 (Oct. 11, 2023) (PFAS reporting rule); 88 Fed. Reg. 47782 (July 25, 2023) (asbestos reporting rule); 82 Fed. Reg. 37520 (Aug. 11, 2017) (inventory reporting rule); 76 Fed. Reg. 54932 (Sept. 6, 2011) (chemical data reporting rule). These reporting rules may also cross reference confidentiality provisions or contain confidential requirements related to the specific reporting requirements at issue. Such reporting rules, however, are

distinct from the CBI Rule at issue here, that was promulgated under 15 U.S.C. § 2613 and pertains exclusively to the confidentiality of business information.[11]

B. Factual Background

1. The Rulemaking

The CBI Rule, generally, established new and amended requirements for the assertion and treatment of CBI claims under the 2016 Amendments to TSCA. EPA published the proposed CBI Rule on May 12, 2022, 87 Fed. Reg. 29078, and the final CBI Rule on June 7, 2023, 88 Fed. Reg. 37155.

The CBI Rule addressed several topics, including substantiation requirements and exemptions, electronic reporting and communication, and the maintenance and withdrawal of CBI claims. It also reorganized the Agency's TSCA CBI regulations. More specifically, the CBI Rule tailors all TSCA CBI claim assertion and review procedures to the requirements of TSCA after the 2016 Amendments and consolidates them—primarily in 40 C.F.R. part 703. Part 703 replaces, for TSCA CBI, many of the general claim assertion and review rules found in EPA's general confidentiality provisions, 40 C.F.R. part 2, subpart B.[12]

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[11] The CBI Rule, in some instances, requires the submission of information, but only in the context of supporting or substantiating CBI claims. *See, e.g.* 40 C.F.R. § 703.5(b).

[12] Additionally, the consolidation of TSCA CBI claim review procedures in part 703 includes some of the review procedures relating to FOIA requests (i.e., CBI claim review required by TSCA section 14(f)(2)(A)).

The CBI Rule requires that confidentiality claims be asserted (and substantiated as necessary) at the time of submission (limited exceptions may apply where such information is collected during an in-person TSCA enforcement inspection). *See* 40 C.F.R. § 703.5. This includes confidentiality claims for specific chemical identity.

2. Regulatory Definition of Health and Safety Study

The proposed rule included extensive discussion regarding limitations on confidentiality protections for health and safety information described in 15 U.S.C. § 2613(b). 87 Fed. Reg. at 29088-89. The proposed rule explained that "the applicable regulations are not uniform in this respect; nor has the statutory basis for these provisions (which itself has changed under the Lautenberg Amendments) been previously enunciated by EPA." *Id*. Accordingly, the Agency proposed to "systematize these provisions, generally allowing CBI claims for very limited categories of information contained within a health and safety study." *Id*. at 29089.

EPA explained its approach:

> While such ancillary information may be contained in a study document submitted under TSCA, EPA does not consider such information to be part of a "health and safety study" as defined in TSCA section 3(8). That definition states that the term 'health and safety study' means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information . . . . This definition does not seek to provide an exclusive list of what is or is not "included" in the health and safety study but instead clarifies that all "underlying" information must be considered part of the study. . . . A

> study report may contain information beyond that which is the basis for the study. Information such as the names of lab technicians neither form the basis for the study nor are relevant to the study results.

Id.

EPA proposed a definition of "health and safety study" in proposed Section 703.3 that specified that certain information was not within the scope of a "health and safety study." *Id*. ("Name of the submitting company; Name of the laboratory; Internal product codes; Names of laboratory personnel; Names and other private information included in study data or reports; Cost or other financial data; and Product development, advertising, or marketing plans.").

In its final rule, EPA kept the exclusions originally proposed but modified the "original proposal to combine similar exclusions and to clarify the intended scope of the exclusions." 88 Fed. Reg. at 37157. EPA excluded from the regulatory definition of "health and safety study":

> (1) The name, address, or other identifying information for the submitting company, including identification of the laboratory that conducted the study in cases where the laboratory is part of or closely affiliated with the submitting company.
>
> (2) Internal product codes (i.e., code names for the test substance used internally by the submitting company or to identify the test substance to the test laboratory).
>
> (3) Names and contact details for testing laboratory personnel and names and other private information for health and safety study participants or persons involved in chemical incidents such as would typically be withheld under 5 U.S.C. 552(b)(6) or under other privacy laws.

> (4) Information pertaining to test substance product development, advertising, or marketing plans, or to cost and other financial data.

40 C.F.R. § 703.3.

3. Process for Deficient Confidentiality Claims

The CBI Rule also established a process for identifying and addressing "deficient confidentiality claims." 40 C.F.R. § 703.5(e). Under this provision, the Agency identified several criteria for deficiency, including, for example, a submitter's failure to provide a public copy of a submission that contains CBI claims. *See* 40 C.F.R. § 703.5(e)(1)(i)-(iv). When a deficient claim is initially identified in a submission, substantive review of CBI claims in that submission is put on hold, and the submitter is given 10 business days to correct the deficiency. If the deficiency is not remedied during this window, the CBI rule explains that "EPA will proceed with review of the submission and may deny the CBI claim(s)." 40 C.F.R. § 703.5(e)(2).

4. Public Disclosure

The CBI Rule also elaborates on circumstances where non-confidential information may be disclosed. For example, 40 C.F.R. § 703.5 states that, if a CBI claim is not asserted at the time of submission, "EPA will not recognize a confidentiality claim, and the information in or referred to in that submission may be made available to the public . . . without further notice." 40 C.F.R. § 703.8(g)

provides for public disclosure of non-confidential information in connection with review of confidentiality claims under 15 U.S.C. § 2613(f).

C. Procedural History

On June 29, 2023, EDF filed a petition for review with this Court. Doc. No. 2005657. On August 4, 2023, ACC filed a petition for review with this Court, Doc. No. 2011601, which was then consolidated with EDF's challenge to the CBI Rule, Doc. No. 2011606. The Chamber of Commerce of the United States and the National Association of Manufacturers were granted leave to participate as amicus curiae in support of Petitioner ACC.

SUMMARY OF ARGUMENT

EPA's CBI Rule gives effect to the statutory commands of 15 U.S.C. § 2613 and the 2016 Amendments. The CBI Rule reasonably balances, in a manner consistent with the statute, disclosure of information to the public and protection of CBI. Collectively, the Petitioners' challenges focus on discrete aspects of the rule as either too protective of CBI or not protective enough. None of these has merit.

First, EPA's regulatory definition of health and safety study is consistent with the statutory definition of "health and safety study." The Agency's regulatory definition ensures public disclosure of "any study of any effect of a chemical substance or mixture on health or the environment or on both." 15 U.S.C. § 2602(8). The regulatory exclusion from a health and safety study of information

that does not bear on the effects of a chemical substance on health or the environment is consistent with the statutory definition, which specifies which information in a study constitutes part of a "health and safety study." The selection of information so excluded was reasonably chosen and narrowly tailored to include information that does not bear on the effects of a chemical substance on health or the environment.

Second, EPA's decision not to require (1) retroactive substantiation; and (2) EPA review for CBI claims for chemical identity that were asserted prior to commercialization and which were later commercialized is supported by the statute. 15 U.S.C. § 2613(c)(2)(G) categorically excludes the identities of pre-commercialized chemical substances from Section 2613(c)(3) substantiation requirements and from Section 2613(g) review.

Third, the CBI Rule enables EPA to reserve judgment regarding the adequacy of a CBI claim initially identified as deficient, under 40 C.F.R. 703.5(e)(2) (using "may" instead of "shall"), until the Agency conducts a review of the claim under 15 U.S.C. § 2613(g). This provision is consistent with Section 2613 and accounts for several potential changed circumstances that may occur after an initial finding of deficiency, including withdrawal of the claim or that, upon review, the initial assessment of deficiency might be revised or become moot. Additionally, the CBI Rule's provisions indicating that EPA may (rather than

must) disclose non-confidential information are consistent with the language and structure of TSCA as a whole and with 15 U.S.C. § 2613 specifically, which addresses, *inter alia*, eligibility for confidential treatment and the procedures EPA must follow *if* the Agency is to disclose information not eligible for confidential treatment. The Section does not mandate disclosure of information based solely on EPA's determination under 15 U.S.C. § 2613 that the information is ineligible for confidential treatment.

Lastly, it was reasonable for EPA to provide in part 703 of the C.F.R. that information referred to in a submission that is not claimed as confidential loses its confidentiality. This is true even where a specific reporting rule[13] requires a company reporting by non-confidential accession numbers to assert a CBI claim for specific chemical identity. EPA reasonably responded to concerns that an entity without knowledge of the underlying chemical identity could waive the CBI claim by stating that such concerns were best addressed in specific reporting rules.

STANDARD OF REVIEW

The final rule is subject to judicial review as set forth in TSCA § 19, 15 U.S.C.§ 2618. For rules promulgated under subchapter I of TSCA, 15 U.S.C. §§

[13] The CBI rule does not contain provisions requiring assertion of CBI claims for chemical identities reported via accession numbers. Where such provisions exist, they are contained in some specific reporting rules, e.g., 40 C.F.R. § 711.15(b)(3)(i). Those rules are not subject to challenge in this action.

2601-29, such as the CBI Rule, TSCA provides that the Court is to review the rule in accordance with the Administrative Procedure Act, 5 U.S.C. §§ 701-706. 15 U.S.C.§ 2618(c)(1)(A). Under the APA, the court may set aside final EPA action found to be "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). The "arbitrary or capricious" standard presumes the validity of agency action, and a reviewing court is to uphold the action if it satisfies minimum standards of rationality. *Am. Farm Bureau Fed'n v. EPA*, 559 F.3d 512, 519 (D.C. Cir. 2009).

Agency action should be upheld where the record reflects that the agency considered all relevant factors and articulated a "rational connection between the facts found and the choice made." *Burlington Truck Lines, Inc. v. United States*, 371 U.S. 156, 168 (1962); *see also Milk Indus. Found. v. Glickman*, 132 F.3d 1467, 1476 (D.C. Cir. 1998) (internal quotation marks and citations omitted).

Courts review an agency's interpretation of a statute it administers for reasonableness. When "traditional tools of statutory interpretation" show that the agency's interpretation is "the best one," the court can uphold the interpretation without resorting to deference principles. *Guedes v. ATF*, 45 F.4th 306, 313 (D.C. Cir. 2022). But agency interpretations that are "reasonable" should also be upheld. *Wash. All. of Tech. Workers v. DHS*, 50 F.4th 164, 192 (D.C. Cir. 2022).

ARGUMENT

I. EDF's Arguments that EPA Is Too Protective of Information Submitted under TSCA Should Be Rejected.

A. EPA Reasonably Determined that Certain Information Is Not Part of a Health and Safety Study and Therefore May Be Claimed as CBI.

Congress excluded any "health and safety study" from the information that may be claimed as CBI. In the CBI Rule, EPA reasonably determined that limited categories of information are not part of a "health and safety study" as that term is defined in TSCA Section 3, 15 U.S.C. § 2602, and are therefore not categorically excluded from confidentiality by 15 U.S.C. § 2613(b)(2). The Agency's approach is supported by the statute and balances the policies of promoting disclosure of health and safety information pertaining to chemicals with concerns about protecting from disclosure information that does not underlie the study document. *Cf.* 88 Fed. Reg. at 37157. It is therefore reasonable.

1. The Statute Supports EPA's Determination That Certain Information Is Not Part of a Health and Safety Study.

a. EPA's Exclusions Are Consistent with the Definition of Health and Safety Study.

TSCA defines a "health and safety study" as:

> any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a

> chemical substance or mixture, and any test performed pursuant to this chapter.

15 U.S.C. § 2602(8).

EDF asserts that the statutory definition of health and safety study must be the entirety of the written document submitted. *E.g.*, EDF Br. at 18 ("'[S]tudy' refers to the entire written report or document submitted to EPA."). But this approach substitutes a lay concept of a "study" for the statutory definition chosen by Congress. *See McDonald v. Household Int'l, Inc.*, 425 F.3d 424, 429 (7th Cir. 2005) (one should not "confuse[] the lay definition of [a] term with the statutory definition").

Congress's word choice in this Section is instructive. The term "health and safety study" is defined with reference to the information being studied, i.e., "the effect of a chemical substance or mixture on health or the environment or on both." As EPA explained in the final rule, parts of a health and safety study that do not evaluate the effect of a substance on health or environment are not, by the definition in Section 3(8), 15 U.S.C. § 2602(8), part of a health and safety study, notwithstanding appearing in the same document. EPA's regulatory exclusions merely flesh out this distinction.

Congress's use of the phrase "including underlying information" further indicates that this definition is not focused on what is within a particular written report or document, but instead on the information and studies forming the basis of

the study. *See* H.R. Rep. No. 94-1679, at 58 (1976) (Conf. Report) ("Any data which *bears on the effects* of a chemical substance on health or the environment would be included.") (emphasis added). Use of the word "'include' can signal that the list that follows is meant to be illustrative rather than exhaustive," *Samantar v. Yousuf*, 560 U.S. 305, 316-18 (2010), it may also be used to "specify particularly that which belongs to the genus." *Montello Salt Co. v. Utah*, 221 U.S. 452, 463-65 (1911); *see also Phelps Dodge Corp. v. N.L.R.B.*, 313 U.S. 177, 211 (1941). Additionally, the term "underlying" is an adjective "used to describe something on which something else is based." Cambridge Dictionary (Online), *underlying*, https://dictionary.cambridge.org/us/dictionary/english/underlying (last visited Jan. 25, 2024). As such, the use of the phrase "including underlying information" means that information that forms the basis of the study would be included in the definition, but that some items of information that do not form the basis of the study are not included in the definition. As EPA explained in the final rule, "[a] study report may contain information beyond that which is the basis for the study. Information such as the names of lab technicians neither form the basis for the study nor is it relevant to the study itself." 88 Fed. Reg. at 37157.

EDF argues that EPA has improperly excluded information that is supposedly necessary to interpret a health and safety study. EDF's criterion for such an evaluation appears to be their desire to use the information. If EDF could

use the information, they argue, it cannot be excluded from the definition of health and safety study, *see* EDF Br. at 20 (focusing on the relevance and utility of information). *See also id*. at 24. In particular, EDF objects to the exclusion of the "identity of the company submitting the health and safety study, along with the laboratory performing the study when the laboratory is 'part of or closely affiliated with the submitting company.'" *Id*. at 21 (quoting 40 C.F.R § 703.3).

This reasoning is faulty. That certain information contained in a study document may be considered *useful* by someone examining a health and safety study does not mean that such information constitutes information bearing on the effects of the chemical substance on human health or the environment or "underlying" the health and safety study per 15 U.S.C. § 2602(8). A study reporting mortality rates of water fleas from exposure to Chemical X is not based on the identity of the laboratory performing the study or even any possible association of such a laboratory with a particular chemical company. The study is based on the methods used, the results reported, the reasoning provided, etc. EDF's assertion that any information useful to them is part of a health and safety study under 15 U.S.C. § 2602(8) is therefore not supported by the statute. The CBI Rule is consistent with clear congressional intent as evidenced by the plain language of the statute.

b. 15 U.S.C. § 2613(b)(1) Supports the Proposition that a Study Document Can Contain Information Not Part of a Health and Safety Study.

EPA's exclusion of certain information from the regulatory definition of "health and safety study," such as the name of the study author or the lab, is further supported by 15 U.S.C. § 2613(b)(1), which recognizes that documents may contain mixed confidential and non-confidential information. That Section provides:

> (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.

15 U.S.C. § 2613(b)(1). Accordingly, the statute itself recognizes that a single document such as a health and safety study can contain a mix of both information that is exempt from the disclosure protection of 15 U.S.C. § 2613(a) and information that is covered by that protection. EPA's regulatory definition is consistent with 15 U.S.C. § 2613(b)(1). *See* 87 Fed. Reg. at 29089; *see also* Response to Comments ("RTC") at 13.

15 U.S.C. § 2613(b)(1) was added as part of the 2016 Amendments to TSCA. Pub. L. 114-182, § 14, 130 Stat. at 481. The addition of Section 2613(b)(1) makes clear that Congress was concerned with balancing the protection of CBI or

trade secrets and public access to health and safety information. *See also* S. Rep. No. 114-67 at 22 (2015) ("The section also makes clear the Committee's intent . . . [to] ensur[e] that all information that qualifies for protection from disclosure that is included in a submission that is otherwise not entitled to protection from disclosure be protected"). Since long before the 2016 Amendments, EPA has consistently protected confidential or otherwise non-disclosable information of the nature at issue here, *see infra* p. 28-29, in a document even when disclosing information not subject to protection. EPA's limited exemptions in the CBI Rule effectuate that careful balancing.

In contrast, EDF's interpretation would render 15 U.S.C. § 2613(b)(1) inoperative in the context of a "health and safety study," contrary to the statute. On its face, Section 2613(b)(1) broadly provides that information that is protected from disclosure under "this section" does not lose its protection simply because it is mixed with information that is not protected from disclosure under the section. *Id*. Instead, read in context Section 2613(b)(1)'s protection continues to apply to other confidential information that may be mixed with the information identified as making up as "health and safety study."

2. EPA's Approach Here is Consistent with Past Practice.

The exemptions in the final rule are consistent with the Agency's long-term policy to ensure non-disclosure of CBI within health and safety study reports. *See*

88 Fed. Reg. at 37157; *see also* RTC at 12. Since the early 1980's, EPA has consistently taken the position that certain, limited categories of information in a health and safety study report, beyond the information identified in 15 U.S.C. § 2613(b)(2), might be entitled to confidential treatment. *See* 40 C.F.R. § 716.55(a)(3), (4) (2022) (repealed 2023); 40 C.F.R. § 720.90(a)(3) (2022) (repealed 2023); 40 C.F.R. § 725.92(c)(2) (2022) (repealed 2023). For example, the Agency's regulations pertaining to health and safety information submitted under TSCA Section 8(d) stated that "[a]ny respondent may assert a confidentiality claim for company name or address, financial statistics, and product codes used by a company. This information will not be subject to the disclosure requirements of section 14(b) of TSCA." 40 C.F.R. § 716.55(a)(3) (2022) (repealed 2023).

EDF asserts that Congress would have explicitly identified information that could be protected from disclosure when it substantially amended TSCA, had Congress wanted to allow additional information to be withheld. EDF Br. at 18-19. EDF's argument lacks merit. Although Congress identified certain information exempt from disclosure that was *part* of a health and safety study, e.g., "processes used in the manufacturing [of the chemical]," 15 U.S.C. § 2613(b)(2), that exemption is distinct from the issue here: whether certain information is part of the

health and safety study at all.[14] Notably, as mentioned above, Congress did not eliminate the application of Section 2613(b)(1)'s general rule regarding the treatment of mixed protected and non-protected information in the context of a "health and data study." Moreover, Congress directly acknowledged EPA's approach to Section 2613(b)(2) in the legislative history. The Senate Report states that "[t]he adoption of this provision of existing law [15 U.S.C. § 2613(b)(2)] *does not signal the Committee's intent to agree or disagree with EPA's interpretation of the provision to date*. Rather, it reflects the significant debate over the scope and interpretation of the provision, *which could not be successfully resolved*." S. Rep. No. 114-67, at 22 (2015) (emphases added). This rebuts EDF's assertion that "EPA's carveouts [in Health and Safety Study] undermine a key purpose of TSCA that was strengthened by the Lautenberg Act," EDF Br. at 19. Congress signaled its awareness of EPA's long-standing approach and did not choose to mandate a different one.

[14] Also, EDF mischaracterizes EPA's argument to the extent it is suggesting that EPA argued that the 2016 Amendments added new exclusions to the denial of protection for information from health and safety studies. As noted *supra*, EPA's interpretation that information in a study document may contain information not subject to 15 U.S.C. § 2613(b)(1) well predates the 2016 amendments to TSCA. And Congress's recognition in 15 U.S.C. § 2613(b)(1) that a document (such as a health and safety study) can contain both confidential and nonconfidential information supports that longstanding position.

3. EPA Reasonably Responded to EDF's Comments.

EDF also asserts that EPA failed to respond to EDF's comments with a reasonable explanation for the health and safety information exclusions. EDF Br. at 21. But EPA robustly explained its regulatory definition. RTC at 12. EPA explained that "[t]hese existing carveouts have permitted companies to redact information that is arguably valuable to them while also not impacting the ability of the public to access and interpret the study document." *Id*. EPA also explained, referencing 15 U.S.C. § 2613(b)(1), "that the definition of health and safety study in section 3(8) does not necessarily include all information contained within a study report, such that other information, like the names of lab personnel, do not constitute information from a health and safety study, but rather (potentially) confidential information that is mixed with the information that is not confidential under section 14(b)(2)." *Id*. at 13.

While EPA did not dispute, for instance, in its response to EDF's comments that certain information excluded from the definition of health and safety study could be relevant to evaluating study reliability or for learning potentially useful information about the subject chemical substance, *see* EDF Br. at 22, the Agency indicated that such information was relevant *for EPA's own use*. RTC at 14. As discussed *supra*, that a member of the public may find a use for certain information

in a study document does not alone cause that information to underlie a health and safety study.

In any event, "an agency need not respond to every comment so long as it responds in a reasoned manner to significant comments received." *U.S. Satellite Broad. Co. v. F.C.C.*, 740 F.2d 1177, 1188 (D.C. Cir. 1984). Here, EPA responded in a reasoned manner to significant comments about its definition of health and safety study by explaining EPA's understanding of the statutory definition of health and safety study. *See* RTC at 12. EPA did not need to "explicitly discuss[] each and every contention" made by EDF on the regulatory definition of health and safety study. *U.S. Satellite Broad. Co.*, 740 F.2d at 1188.

B. TSCA Does Not Require Retroactive Substantiation and Review of Chemical Identity CBI Claims That Were Exempt When the CBI Claim Was Asserted.

Congress expressly excluded from 15 U.S.C. § 2613(c)(3) substantiation requirements for CBI claims for chemical identity that are asserted prior to the chemical's use in U.S. commerce. However, CBI claims for chemical identity asserted after the chemical is introduced into commerce must be substantiated and reviewed by EPA. Because Congress did not allow 15 U.S.C. § 2613(c)(3) substantiation requirements to be applied *retroactively* at the time of commercialization, EPA did not include such a requirement in the CBI Rule. EPA's rulemaking here balances the statutory protection afforded to CBI claims

for specific chemical identity that are asserted before the chemical is put into U.S. commerce with the need to ensure that the CBI claims asserted after a chemical substance has entered U.S. commerce are properly substantiated and subject to review by EPA.

1. Claims For Chemical Identity Asserted Before the Chemical Substance Is First Offered for Commercialization Are Not Subject to Substantiation and Routine Review.

15 U.S.C. § 2613(c)(2) carves out classes of information that "shall not be subject to substantiation requirements" and that, per Section § 2613(g)(1), are exempt from routine claim review. Among the classes of information exempt from CBI claim substantiation and routine CBI claim review is pre-commercialization specific chemical identities "[p]rior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the 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." 15 U.S.C. § 2613(c)(2)(G).

This provision categorically exempts from substantiation and 15 U.S.C. § 2613(g) review a CBI claim for chemical identity that is asserted prior to the chemical being offered for commercial distribution. A chemical identity claim in a pre-commercialization submission continues to remain exempt from substantiation requirements and 15 U.S.C. § 2613(g) review after the chemical is offered for

commercial distribution unless and until a post-commercialization submission CBI claim for that same chemical is received or some other statutory trigger applies.[15] 15 U.S.C. § 2613(c)(2)(G).

2. EPA's Interpretation Is Consistent with the Statute and Reasonable.

EPA's interpretation that a CBI claim for chemical identity asserted prior to commercialization does not automatically expire once the chemical substance is commercialized is supported by the language in TSCA Sections 2613(c)(2) and (g)(1).

15 U.S.C. § 2613(c)(2) provides that a CBI claim for information described in subsections (A) through (G) "shall not be subject to substantiation requirements."[16] *Id*. Use of "shall not" in Section 2613(c)(2) creates a permanent class of exempt claims unless there is a separate, independent trigger for substantiation and review of the exempt claim.

EDF claims that the "plain language" of TSCA requires that, once commercialization has occurred, EPA must return to the previously submitted documents, ask the submitter to substantiate the claim, and conduct a Section

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[15] For example, after commercialization, EPA would review the initial pre-commercialization submission if one of the triggers for statutorily mandated review under Section 14(f)(2), 15 U.S.C. § 2613(f)(2), were met.

[16] 15 U.S.C. § 2613(g)(1)(C), then makes "information described in subsection (c)(2)(G)" ineligible for CBI review under Section 2613(g).

2613(g) review of that submission. EDF Br. at 26-27. But EDF's argument on this point rests on an inaccurate statutory construction. The "prior to" language that EDF relies upon to support its argument appears in the description of the category that is exempt from substantiation requirements. As such, the phrase "prior to" modifies the category of information referenced in Section 2613(c)(2)(G) and is relevant only to defining the category of information subject to the exemption. The phrase does not modify the substantiation exemption itself, which appears in the introductory text in § 2613(c)(2), or create an exemption window, such that a previously exempt claim must be revisited once the time window elapses.

EDF's argument would read language into Section 2613(c)(2)(G) that is not there. Congress could have written the exemption for pre-commercialization chemical identity claims as follows: "[p]rior to the date on which a chemical substance is first offered for commercial distribution, [*a claim for*] the specific identity of chemical substance . . . ." It did not do so. Thus, contrary to their assertion, Congress did not need to say the exemption is "permanent."

EDF's "plain language" assertion also fails when Section 2613(c)(2)(G) is compared to other provisions in 15 U.S.C. § 2613. Section 2613(g)(1) governs CBI claim review, including, notably, the timing of such review. Section 2613(g)(1)(A) plainly states that CBI review shall occur "not later than 90 days after the receipt of *a claim* under subsection (c)." (emphasis added). This review deadline could not be

met if Section 2613(c)(2)(G) were read to require a retroactive Section 2613(g) CBI claim review upon commercialization of a chemical substance that was eligible for the pre-commercialization exemption. Commercialization can occur years after the assertion of the chemical identity CBI claim.[17]

If Congress had intended that an alternate review timeframe be created for an "expired" exemption, it would have said so. This is especially true for 15 U.S.C. § 2613(g), which contains extensive timeframes and procedural requirements for CBI claim review. Additionally, Section 2613(f)(2) addresses several circumstances under which previously submitted CBI claims may or must be reviewed. Yet, the Section notably omits any trigger for either discretionary or mandatory review of previously submitted CBI claims tied simply to commencement of commercialization as a general matter. 15 U.S.C. § 2613(f). Congress's omission of previously submitted CBI claims tied simply to commencement of commercialization from the list of other circumstances where review of such CBI claims is allowed or required strongly undermines EDF's view that CBI claim review is somehow *sua sponte* triggered upon commercialization.

[17] Most TSCA Section 2613(c)(2)(G) CBI claims accompany Premanufacture Notices, which are reviewed by EPA with a 90-day review period, 15 U.S.C. § 2604(i)(3), and whose subject chemical substances cannot be manufactured before EPA has allowed such manufacture. 15 U.S.C. § 2604(a)(3). Thus, it would be impossible for chemical identities subject to the Section 2613(c)(2)(G) exemption to be reviewed within the Section 2613(g)(1)(A) deadline.

The flaw in EDF's argument is further highlighted by the unchallenged interpretation that 15 U.S.C. § 2613(c)(3) requires substantiation *at the time of submission* of the request for CBI confidentiality. *See also* 15 U.S.C. § 2613(c)(2)(G) (no substantiation required for pre-commercialization substance if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under Section 2604). In contrast, when a person submits a notice of commencement of commercialization, they are not required to resubmit information previously reported to the Agency. *Compare* 40 C.F.R. §§ 720.45 and 720.50(a)(1) (requiring, pre-commercialization, an extensive amount of information in order for the Agency to substantively review the chemical, including the submission of "all test data in the submitter's possession or control which are related to the effects on health or the environment" of the chemical), *with* 40 C.F.R. § 720.102(c)(1) (requiring a limited set of data, including the identity of the chemical and the company name). EDF's position would require substantiation for a prior-submitted claim at the time a notice of commencement is filed. But, there is no statutory basis for that position, and it is in fact inconsistent with the statutory requirement to substantiate at the time of submission.

Moreover, Section 2613(e)(1)(A) provides that protection for information exempt from substantiation in Section § 2613(c)(2), such as information submitted prior to commercialization, is not subject to the 10-year expiration period that

applies to CBI claims for other information. *See* 15 U.S.C. § 2613(e)(1)(B) (CBI claims for other types of information expire unless reasserted.). Congress did not exclude Section § 2613(c)(2)(G) chemical identities from this exemption to the 10-year reassertion requirement, further indicating its intent that the Section 2613(c)(2)(G) exemption from routine substantiation and review does not expire.

EDF's argument is further undermined by Congress's clear direction not to impose overly burdensome substantiation requirements. Section 2613(i)(1)(B) specifically prohibits the Agency from "impos[ing] 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." Conversely, Congress was specific in other parts of Section 2613 when it wanted to impose additional substantiation requirements. *See, e.g., id*. at §§ 2613(e)(2)(B)(i) and (f)(2). Here, the statute expressly exempts substantiation at the time of submission and has no requirement for substantiation of that claim *at the time of commercialization*. TSCA is clear that the Agency may not require routine substantiation for the previously submitted claims.

Here, "traditional tools of statutory interpretation" show that EPA's interpretation is "the best one." *Guedes*, 45 F.4th at 313. Accordingly, though EPA's interpretation is at least reasonable, the court may uphold the interpretation without resorting to deference principles. *Id*.

3. Interested Parties Are Not Denied Access to Health and Safety Studies and Other Information Submitted Pre-Commercialization.

EDF argues that EPA's interpretation of 15 U.S.C. § 2613(c)(2)(G) will lead to CBI claims for chemical identity in (pre-commercialization) Premanufacture Notices remaining in place "indefinitely even after the chemical enters commercial production," depriving the public of "access to information key to understanding the health and environmental effects of new chemicals" contained in the pre-commercialization submission. This assertion does not withstand scrutiny.

No confidentiality claim asserted under 15 U.S.C. § 2613, even one exempt from upfront substantiation and routine review under Sections 2613(c)(1)(G) and 2613(g)(1), is irrevocably excluded from substantiation and review requirements. Section 2613(f) contains several triggers for substantiation and review of exempt CBI claims.[18] Notable among these triggers is 15 U.S.C. § 2613(f)(2)(A), which requires substantiation and review upon filing of a request under the FOIA. Anyone can file a FOIA request for records that include the chemical identities in Premanufacture Notices claimed as CBI, and EPA thereby becomes obligated under the statute to issue confidentiality determinations regarding the chemical identities included in the requested records. 15 U.S.C. § 2613(f)(2)(A). If, upon

[18] TSCA expressly makes these exemptions "[s]ubject to subsection (f)." 15 U.S.C. § 2613(c)(1)(G).

CBI review, EPA determines that the chemical identity is not entitled to confidential treatment, the chemical identity may be made available to the public, including in copies of the Premanufacture Notices that were the subject of the FOIA request.

Additionally, if a CBI claim for specific chemical identity is asserted at the time of commercialization and approved (i.e., the chemical identity is determined to be eligible for confidential treatment), the statute provides another avenue to connect the chemical substance to the documents submitted in new chemical applications. Section 2613(g)(4)(A)(i) provides for unique identifiers to be assigned once EPA approves a confidentiality claim for specific chemical identity. EPA is required to link nonconfidential information pertaining to that substance to that unique identifier. 15 U.S.C. § 2613(g)(4)(D). Thus, even where the specific chemical identity remains undisclosed, the unique identifier can be used to identify nonconfidential information concerning that chemical substance.

If a CBI claim for chemical identity is approved in a Notice of Commencement of Manufacture or Import, the unique identifier would link documents with information relevant to the chemical substance such as the notice

and the prior new chemical submission.[19] *See* 15 U.S.C. § 2613(g)(4)(A)(ii) (requiring the Administrator to "apply that [unique] identifier consistently to all information relevant to the chemical substance"). Congress clearly contemplated a scenario where a specific chemical identity remained confidential after review and that, despite the chemical identity remaining confidential, there needed to be a mechanism for the public to tie information back to any prior submissions. The unique identifier provision is how Congress chose to create a link to those submissions, rather than EPA conducting a retroactive CBI claim review of the prior submissions. Thus, while the unique identifier provision does not disclose the specific chemical identity in pre-commercialization documents, it explicitly provides the public with the ability to "make use of information like health and safety studies, even after such chemicals are in commerce" per the need identified by EDF in its brief, *see* EDF Br. at 33.

4. EPA Reasonably Addressed its Past Regulations and EDF's Comments.

EDF raised several procedural issues regarding EPA's response to comments on this issue, each of which are without merit. EDF Br. at 28-31. EDF argues that EPA's pre-2016 Amendment regulations "stated that a claim of confidentiality for

[19] The Notice of Commencement of Manufacture or Import itself is also connected to the Premanufacture Notice, in that they have the same case number (P-xx-xxxx), and receipt of both is published in the Federal Register and Chemview.

a chemical identity . . . made without substantiation would only last until the chemical was commercialized—at which point the claim would then be subject to reassertion and substantiation." EDF Br. at 28. As an initial matter, because EPA's approach is required by the statutory language (discussed *supra* at Section I.B.2.), the Court need not engage with EDF's procedural arguments, which, if accepted, would require EPA to adopt regulations contrary to statutory language. Importantly, the regulations cited by EDF, 40 C.F.R. §§ 720.90(b)(2) and 720.85(b), *see* EDF Br. at 28, were all enacted *prior to* the new language in 15 U.S.C § 2613, set forth in the 2016 Amendments, which mandated EPA's current approach.

Contrary to EDF's argument, EDF Br. at 28-31, EPA acknowledged and explained that it was changing a provision that had been superseded by the 2016 Amendments (and that was therefore no longer followed), 88 Fed. Reg. at 37162. Importantly, EPA could not "have maintained its requirement under [40 C.F.R.] subsection 720.90(b)(2) that the claim must be reasserted upon commercialization," EDF Br. at 30, given Congress's statutory command, *see* Section I.B.2. *supra*.

EPA also responded to EDF's comment asserting that the removal of these provisions would transform a temporary exemption into an indefinite one. EDF Br. at 30. EPA explained that "[s]uch earlier claims may be reviewed or re-reviewed,

but not automatically—instead, they could be reviewed under either the mandatory or discretionary provisions of section 14(f).” RTC at 27. EPA clearly explained that 15 U.S.C. § 2613(c)(2)(G) does not provide a blanket exemption from all CBI review and that “there is no mandatory trigger in 15 U.S.C. § 2613(f)(2) relating to distribution in commerce.” *Id.*

As the U.S. Supreme Court noted in *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221-22 (2016), “[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change[, and] ‘need not always provide a more detailed justification than what would suffice for a new policy created on a blank slate.’” (internal citations omitted). EPA clearly meets that standard as the Agency acknowledged changes to its regulations to, among other reasons, bring TSCA confidentiality regulations in line with the changes to 15 U.S.C. § 2613 brought about by the 2016 Amendments.

In its brief, EDF asserts that EPA failed to consider the negative impacts on the public’s ability to use information, EDF Br. 31-33, and that EPA failed to acknowledge that there are different bases for confidentiality pre- and post-commercialization, *id*. at 33. Importantly, EDF never raised these arguments during the rulemaking. *See* EDF Comments at 32-33 (EPA-HQ-OPPT-2021-0419-0050). As a result, EDF waived these arguments and deprived EPA of the ability to squarely address them during the rulemaking. *See Nat’l Wildlife Fed’n v. EPA*, 286

F.3d 554, 562 (D.C. Cir. 2002) ("It is well established that issues not raised in comments before the agency are waived and this Court will not consider them."); *see also Nuclear Energy Inst., Inc. v. EPA*, 373 F.3d 1251, 1290 (D.C. Cir. 2004).

But, even if EDF had raised these arguments, EPA would have had no choice but to explain that EDF's policy contentions cannot overcome the statutory mandate that the Section 2613(c)(2)(G) exemption does not expire upon later commercialization of the chemical substance.

C. The CBI Rule Gives EPA Appropriate Discretion to Review Confidentiality Claims and Recognizes that TSCA Does Not Require Automatic Public Disclosure.

1. The CBI Rule Reasonably Allows EPA To Use the Full CBI Review Period to Address Claims with Identified Deficiencies.

The CBI Rule requires assertion and substantiation of CBI claims pursuant to TSCA, and EPA's review of such claims is done in accordance with the requirements of 15 U.S.C. § 2613. TSCA requires EPA to deny a deficient CBI claim that was not remedied by a submitter. If a claim is deficient, EPA will deny the claim in accordance with 15 U.S.C. § 2613. Contrary to EDF's suggestion, the relevant regulatory provision does not assert discretion to approve deficient claims. EDF Br. at 34 (citing 50 C.F.R § 703.5(e)(2)). The Agency reasonably retained flexibility, in a manner consistent with the statute, to address claims that may not have met all the assertion requirements in 15 U.S.C. § 2613(c) during the statutory

review period for CBI claims. 40 C.F.R. § 703.5(e). This balances the Congressional mandate that claims meet the assertion requirements in 15 U.S.C. § 2613(c) with the administrative requirement that an adjudication be based upon the facts before the adjudicator at the time of adjudication. *See Safe Extensions, Inc. v. FAA,* 509 F.3d 593, 604 (D.C. Cir. 2007) (informal adjudications must be supported by substantial evidence in the record before the agency).

TSCA affords EPA 90 days to review CBI claims. 15 U.S.C. § 2613(g)(1)(A). EPA has until the end of that period to "review and approve, approve in part and deny in part, or deny the claim or request." *Id.* EPA's CBI Rule provides flexibility for the Agency to handle multiple scenarios that may occur during the 90-day review period. The CBI Rule does not, as EDF alleges, grant EPA discretion to approve CBI claims that fail to meet the statutory requirements for confidential treatment. Rather, the term "may deny" as used in 40 C.F.R. § 703.5(e) applies only to what happens at the end of the 10-day correction window provided by the CBI Rule. The provision does not grant EPA discretion to approve a claim that is found to be deficient upon review. EDF Br. at 35. It simply allows EPA the full 90-day review period to make a final determination and accommodates the possibility that, based on the facts at the time of such review, EPA may determine that the CBI claim is not deficient.

As the Agency explained in the response to comments, any number of intervening factors may arise during the 90-day review period that may require Agency consideration. For example, as EPA has long observed, "innocent mistakes and technical errors do happen from time to time [in the assertion and substantiation of CBI claims], and . . . immediately releasing information for which a CBI claim had evidently been attempted would be unduly punitive." RTC at 34. Therefore, as part of the CBI Rule, EPA allows a reasonable, 10-day window of opportunity for submitters to fix minor mistakes or technical errors. 40 C.F.R. § 703.5.

While EDF doesn't challenge the opportunity provided in the CBI Rule to remedy an identified deficiency, EDF argues that, if a submitter fails to remedy a deficiency in a CBI claim, TSCA requires that EPA deny the claim. EDF Br. at 34. While EPA does not disagree that TSCA requires EPA to deny a deficient CBI claim that was not remedied by a submitter, EPA takes issue with EDF's argument that the outcome of the Agency's Section 2613(g) review is predetermined. EDF's approach would unreasonably require EPA to, in effect, make an advance decision to deny all claims initially identified as deficient, regardless of any intervening factors that may occur after the 10-day hold. Such a result is not required by statute and would be illogical if something occurs in the remaining days of the review period that either eliminates the need to make a determination or influences the

determination itself. For example, as explained in the response to comments, a submitter may choose to withdraw a CBI claim and, thus, eliminate the requirement for EPA to complete a CBI review, or during the 90-day window, as EPA fully evaluates the CBI claim, the Agency may determine it was incorrect in its initial analysis. *See* RTC at 41. Thus, EPA reasonably retained discretion to withhold final judgment on a claim until the 15 U.S.C. § 2613(g) review is conducted.

2. TSCA Does Not Require Automatic Public Disclosure of Non-confidential Information.

TSCA does not require EPA to disclose all non-confidential information. EDF's argument that the Agency replaced provisions requiring mandatory disclosure with discretionary disclosure provisions without adequate explanation, EDF Br. at 40, is baseless. TSCA is explicit as to when EPA is required to disclose information. The CBI Rule is consistent with these statutory provisions, as the Agency explained during the rulemaking process. *See, e.g.,* RTC at 51. EPA balanced the exclusions from the protections from disclosure in 15 U.S.C. § 2613 with the limited public disclosure requirements in other TSCA provisions.

TSCA provides guidelines for when EPA must protect confidential information. Section 2613(a) states, in relevant part, "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." Therefore, if a submitter's claim for confidential treatment of certain information meets the legal requirements of FOIA Exemption 4 and 15 U.S.C. § 2613(c), EPA "shall not disclose" such information.

TSCA permits, but does not require, the disclosure of all information that falls outside of the Section 2613(a) prohibition on disclosure. Instead, where Congress mandated disclosure of certain information, it expressly stated so in select sections of the statute. For example, Section 2613(d), addresses exceptions to protection from disclosure for information that is claimed or otherwise treated as CBI. 15 U.S.C. § 2613(d)(1)-(9). Eight of these exceptions use the mandatory language "shall be disclosed," while the other states that certain information "may be disclosed." *Id*. Another mandatory disclosure provision, 15 U.S.C. § 2625(j), applies only to the information described in paragraphs (1)-(5) of that subsection.[20] Section 2607(b) also includes mandatory public disclosure provisions. *See* 15 U.S.C. § 2607(b)(4)(B)(iv); *see also,* 15 U.S.C. § 2607(b)(7). (Notably, the CBI

[20] Section 26(j) expressly provides that it applies to information not entitled to confidentiality under 15 U.S.C. § 2613: "Subject to section 2613 of this title, the Administrator shall make available to the public . . . ." 15 U.S.C. § 2625(j). This provision makes clear that, where Congress wants non-CBI TSCA information to be made public, it states so expressly.

Rule could not and explicitly does not contradict the disclosure provisions in sections 2613(d), 2625(j), or 2607(b)). Section 2613(b)(4), regarding confidentiality of information relating to bans and phase-outs, which allows rather than requires disclosure, states only, "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." 15 U.S.C. § 2613(b)(4)(A). Therefore, EDF's assertion that the discretionary language at 40 C.F.R. § 703.5 and § 703.8(d) is contrary to the statute is without merit where there is no mandatory disclosure provision for all non-confidential information.

Similarly, 15 U.S.C. § 2613(b)(5) states, "If a request is made to the Administrator under section 552(a) of Title 5 [(FOIA)] 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." In this provision, Congress chose not to mandate disclosure. Instead, it explicitly eliminated one potential basis for denial, implicitly recognizing that other bases for denial may exist. That Congress intended to acknowledge that other bases for denial may exist is supported by the fact that earlier versions of TSCA included broader disclosure requirements that were ultimately not included in the final bill. *See*, *e.g.*, S. 697, 114th Cong. (2015) (introduced version) ("Any information otherwise eligible for protection under this

section and contained in a submission of information described in this subsection shall be protected from disclosure, if the submitter complies with subsection (d), subject to the condition that information in the submission is not eligible for protection against disclosure *shall be disclosed.*") (emphasis added). As these varied provisions, and legislative history, illustrate, Congress was deliberate in how it spoke to disclosure of information.

EDF leans on legislative history to argue that there is a "requirement that EPA make publicly available information that does not qualify for confidentiality." EDF Br. at 37. But legislative history cannot add a requirement that the statutory text does not include.[21] *See Ratzlaf v. United States*, 510 U.S. 135, 147-48 (1994) (courts should "not resort to legislative history to cloud a statutory text that is clear"); *Davis v. Mich. Dep't of Treasury*, 489 U.S. 803, 808–09 n.3 (1989)

[21] Nor does the legislative history cited by EDF even purport to interpret the statute as requiring affirmative disclosure of information. At most, it states that certain members of Congress "expect EPA to continue its current practice of affirmatively making public information that is not or no longer protected from disclosure as expeditiously as possible," 162 Cong. Rec. 7985 (2016), and that the Senate Committee considering an early version of the Lautenberg amendments sought to "maximize public availability of health and environmental information," S. Rep. No. 114-67, at 21 (2015). Information determined under Section 2613(g) not to be entitled to confidential treatment *is* available to the public, through a FOIA request for example, with or without prior action by EPA. Moreover, EPA routinely makes chemical information available to the public through its ChemView system, https://chemview.epa.gov/chemview/, fulfilling the hopes of the 2015 Senate Committee.

("Legislative history is irrelevant to the interpretation of an unambiguous statute.").

In addition to providing definitive guidelines for disclosure of information, Congress granted EPA broad discretion to promulgate rules regarding the treatment of claims for confidentiality. 15 U.S.C. § 2613(c)(1)(A). EPA has exercised this authority in a manner fully consistent with the plain language of the statute. EDF's argument that the Agency did not adequately acknowledge and explain regulatory changes is without merit and at odds with legal standards.

3. EPA Sufficiently Responded to EDF's Comments that the Regulations Allowed EPA to Improperly Approve Confidentiality Claims.

EPA sufficiently responded to EDF's comment on 40 C.F.R.§ 703.5(e)(2). As EDF noted in its brief, EPA explained in the Response to Comments that, "the language employed was intentional, to allow the possibility that a CBI claim deficiency might be overcome or that the claim might no longer need a determination (such as if it were withdrawn, or the submitter made a persuasive argument that it was exempt from substantiation requirements)." EDF Br. at 39; RTC at 41. While EDF may not agree with the Agency's position, this does not mean that EPA failed to meet the applicable legal requirements for such a response. *See, e.g., City of Waukesha v. E.P.A.*, 320 F.3d 228, 257-58 (D.C. Cir. 2003) ("The Agency 'need not address every comment, but it must respond in a

reasoned manner to those that raise significant problems.'") (internal citations omitted); *Ass'n of Private Sector Colleges and Univs. v. Duncan*, 681 F.3d 427, 441 (D.C. Cir. 2012) ("An agency's obligation to respond, however, is not 'particularly demanding.'") (internal citations omitted); *U.S. Satellite Broad. Co.*, 740 F.2d at 1188. EPA sufficiently responded to EDF's comment on this provision of the CBI Rule.

Furthermore, and contrary to EDF's argument, the Agency's responses explained in detail why and how the CBI Rule would result in certain regulatory changes. In one such instance, for example, EDF correctly noted that language in a proposed regulation implied that disclosure under certain sections of TSCA was discretionary. In response, the Agency revised the proposed regulation to clarify the non-discretionary nature of those sections of the statute. *See* RTC at 6. In another instance, for example, EPA acknowledged and responded to a comment regarding permissive language, noting that "the language employed was intentional." RTC at 41. But EPA clarified language such as "may be" "is not intended to suggest that disclosure is in doubt *when the information is requested,* but rather to provide EPA with discretion and flexibility on the timing for proactively or unilaterally disclosing data . . . ." *Id.*

Additionally, EPA responded to a comment in support of "retaining existing CBI provisions in 40 CFR 704.7, 716. 55, and 790.7" on the grounds "that those

provisions are more specific than the parallel provisions in 40 CFR 703." RTC at 46. EPA explained in response that "[p]re-existing TSCA rules do not fully implement the new requirements under section 14" and that the newly-enacted 15 U.S.C. § 2613 provides that "CBI claims in a submission must generally be denied before the submission is disclosed to the public." *Id*. The regulations that EDF argues should have been maintained, "40 CFR parts 704, 716, and 717[,] each had provisions pre-dating the Lautenberg amendments that required notice to the submitting company concerning deficiencies with public copies and permitting correction of the problem." RTC at 46. Thus, not only could these provisions not be retained, but EPA adequately explained why.

II. This Court Should Reject ACC's Arguments that EPA Is Not Protective Enough of Information Submitted under TSCA.

A. The CBI Rule Protects Confidential Chemical Identities, and EPA Reasonably Decided to Address ACC's Concerns in Specific Reporting Rules.

The CBI Rule protects confidential chemical identities as required by 15 U.S.C. § 2613. Consistent with longstanding EPA regulatory authority,[22] where information is submitted without a confidentiality claim, the rule provides that EPA will not recognize a confidentiality claim and the information in or referred to in that submission may be made available to the public. 40 C.F.R. § 703.5. That

[22] *See, e.g.*, EPA confidentiality regulations at 40 C.F.R. § 2.204.

information may be made available to the public even if it had been claimed as confidential by another party. Accordingly, EPA generally requires that if a company reports a confidential specific chemical identity by non-confidential accession number, the company must assert a CBI claim for the underlying specific chemical identity.

Petitioner ACC's challenge focuses on the application of the CBI claim assertion and substantiation requirements to entities that report via accession number and do not have knowledge of the underlying chemical identity. For simplicity, we refer to this issue as the "knowledge issue." EPA reasonably determined that it would be best to address those concerns and circumstances in later rules that contain specific tailored reporting requirements.

1. EPA's Process for the Assertion of Confidential Claims for Chemical Identity Is Reasonable and Unchanged.

a. EPA May Require that Confidential Chemical Identities Reported via Nonconfidential Accession Numbers Be Claimed as Confidential in Order to Maintain Confidentiality.

TSCA provides EPA with authority to promulgate rules regarding confidentiality claims. 15 U.S.C. § 2613(c)(1)(A). EPA issued its part 703 regulations in accordance with this broad authority delegated to the Agency by Congress.

ACC argues that EPA lacks authority to require that companies reporting specific chemical identities via non-confidential accession numbers assert confidentiality claims for the underlying chemical identity and, if they do not, to move those chemical identities to the public version of the Inventory. ACC Br. at 16, 20, 24, and 27. In so arguing, ACC misunderstands the nature of the reporting in question. The reported accession numbers are proxies for the specific chemical identities, which are both: (1) the information that is ultimately the subject of the reporting rule; and (2) the information for which confidentiality is being sought.

EPA exercised its authority to require that a person wishing to protect a confidential chemical identity from disclosure assert a confidentiality claim to protect that specific chemical identity. *See* 40 C.F.R. § 703.5. That the chemical substance on the confidential portion of the Inventory is identified to EPA by a nonconfidential accession number does not alter the fact that the subject of both the report and the claim is the underlying specific chemical identity. Where a person wishes to protect the specific chemical identity from disclosure, the Agency is acting consistent with 15 U.S.C. § 2613(c) to require a confidentiality claim for the chemical identity being asserted.

While ACC is concerned about the submission of reports using only accession numbers, requirements to report chemical identities via accession number are created by other rules that are not subject to challenge in this action. As

explained in detail, *see infra* p. 59, the CBI Rule does not contain any requirements to report chemical identity information to EPA instead. As the Agency explained, specific reporting rules are best suited to account for the varied relevant factors of the required reporting, including reporter knowledge.

b. EPA Has Not Changed its Position.

EPA has long required assertion and substantiation of CBI claims for chemical identity reported only by accession number, regardless of the submitter's knowledge of the underlying specific chemical identity. Nevertheless, ACC argues that the Agency has changed its position regarding assertion of confidentiality claims by persons who might not have knowledge of the specific chemical identities they are reporting to EPA. ACC Br. at 28. ACC also argues that EPA has failed to acknowledge or explain this change of position. On both counts, ACC is wrong. EPA has not changed its position. Additionally, the Agency explained its position in the RTC. *See* RTC at 16.

Since 2011, EPA has required both assertion and substantiation of confidentiality claims for chemical identity reported only by accession number.[23] Under 40 C.F.R § 711.15(b)(3)(i), "[s]ubmitters who wish to report chemical substances listed on the confidential portion of the TSCA Inventory will need to

[23] For an example of post-2016 rulemaking with similar requirements, see generally TSCA Inventory Notification (Active-Inactive) Requirements, 82 Fed. Reg. 37520.

report the chemical substance using a TSCA Accession Number" that is listed on the public portion of the Inventory. 76 Fed. Reg. 50816, 50872 (Aug. 16, 2011). This same rule: (1) provided that information not claimed as confidential may be made "public without further notice to the submitter"; and (2) required that all confidentiality claims for chemical identity be substantiated. *Id*. at 50878-79 (codified at 40 C.F.R. §§ 711.30(e) and 711.30(c)). Thus, a confidentiality claim for chemical identity requires that a submitter claim as CBI, and substantiate, the underlying specific chemical identity (reported via accession number).

This was discussed in the preamble for the 2011 rule:

> In cases where a chemical substance is listed on the confidential portion of the TSCA Inventory, submitters are to report the chemical substance's TSCA Accession Number and generic name, which are listed on the non-confidential portion of the TSCA Inventory and are included in SRS [the Substance Registry Services]. In order to continue to protect the confidentiality of the underlying specific chemical identification information (i.e., the CASRN and specific chemical name), the submitter must claim the chemical identity as CBI and complete the upfront substantiation. Doing so will maintain a confidentiality claim for the underlying CASRN and specific chemical name on the confidential portion of the TSCA Inventory (the TSCA Accession Number and generic chemical name remain non-confidential). Failure to identify the chemical identity as CBI and complete the upfront substantiation will waive any CBI claim to the chemical identity and will result in the transfer of the chemical substance from the confidential portion of the TSCA Inventory to the non-confidential, publicly releasable, portion of the TSCA Inventory.

76 Fed. Reg. at 50825.

When explaining the change from allowing confidential chemical identity reporting via accession number to requiring the use of the accession number, EPA explicitly acknowledged in the 2011 final rule the possibility that persons reporting specific chemical identities via accession numbers might not know the specific chemical identity:

> The proposed rule, at 40 CFR 711.15(b)(3)(i), provided that "[a] submitter under this part may use an EPA-designated TSCA Accession Number for a confidential chemical substance in lieu of a CASRN when a CASRN is not known to or reasonably ascertainable by the submitter."

76 Fed. Reg. at 50830. This regulatory scheme has not changed.

ACC attempts to bolster its argument by citing EPA's TSCA Inventory Notification (Active-Inactive) Requirements rule under Section 8(b) of TSCA, 82 Fed. Reg. 37520, which addresses new requirements in the 2016 Amendments to identify chemical substances on the Inventory with active manufacture. *See* 15 U.S.C. § 2607(b)(4). ACC notes that the Agency "outlined two reporting options for entities that lack knowledge of the chemical identity of the substance for which it is required to report "because of third party CBI[.]" ACC Br. at 29.

In fact, ACC's discussion of the TSCA Inventory Notification (Active-Inactive) Rule actually supports EPA's approach to the knowledge issue. The TSCA Inventory Notification Rule is a reporting rule that contains specific reporting requirements and thus, EPA determined it was appropriate to provide

alternative reporting options where companies may lack knowledge of the specific chemical identity and may not be in a position to waive a claim for information they do not know. This *is* the approach taken by the Agency in the challenged rulemaking. The Response to Comments for the CBI Rule states that:

> EPA believes that the best way to address commenters' concerns is to include measures in specific TSCA reporting rules that take into account the reporting entity's potential lack of knowledge, where such measures are necessary. Addressing the issue in the context of specific reporting rules will allow EPA to take into consideration the unique reporting context for the rule, such as the attributes of specific reporters.

RTC at 18. Just as EPA addressed ACC's concern regarding the knowledge issue in the TSCA Inventory Notification Rule in *that* rule, EPA merely submits that its rule-by-rule approach to the issue is reasonable. (Reporting rules require the submission of certain types of information to EPA. *See supra* p. 14. As discussed *infra* p. 63-64, EPA provided some practical examples in the Response to Comments of how these issues might be addressed in particular reporting rules.)

Given that EPA has not changed its position regarding the knowledge issue, the Agency was not required to address, or otherwise explain, its position. Nevertheless, EPA fully explained its position on this issue in the Response to Comments.

2. The CBI Rule Ensures Protection of Confidential Chemical Identities.

a. EPA May Disclose Information that Is Not Claimed as CBI.

TSCA protects from disclosure only that information for which a CBI claim is asserted. 15 U.S.C. § 2613(c). Consistent with the statute, the CBI Rule requires that confidentiality claims be asserted at the time of submission. 40 C.F.R. § 703.5. This includes confidentiality claims for a specific chemical identity. Where no claim is asserted, the statute does not require protection of the information, and, consistent with the statute, the CBI Rule states that such information may be disclosed. 40 C.F.R. § 703.5; *see also supra* pp. 46-47.

EPA has implemented 15 U.S.C. § 2613 in this manner since the enactment of the statute. *See* 42 Fed. Reg. 64572, 64591 (Dec. 23, 1977); 50 Fed. Reg. 9944, 9950 (Mar. 12, 1985). "EPA has consistently maintained and provided public notice of its position that if *any* submitting entity chooses not to assert and/or substantiate a confidentiality claim for a chemical identity as required by TSCA section 14, the chemical identity is no longer entitled to confidential treatment and may be published on the public portion of the TSCA Inventory." 88 Fed. Reg. at 37158. This is the case whether the reporter is the manufacturer or downstream processor. "If another person reveals to the public that a confidential chemical substance is manufactured or processed for nonexempt commercial purposes in the

United States, then the specific chemical identity would no longer be eligible for confidential protection." *Id.* Even in a situation where one or more manufacturers meet the requirements, *see* ACC Br. at 24-25, if another entity fails to meet those requirements, then the chemical identity is no longer confidential and subject to disclosure.

b. The CBI Rule Does Not *Require* Disclosure of a Chemical Identity When a Person Lacking Knowledge of that Chemical Identity Fails to Assert a CBI Claim for the Information.

The CBI Rule does not *require* disclosure of a chemical identity when a person lacking knowledge of that chemical identity fails to assert a CBI claim for information. Instead, the CBI Rule merely provides a general framework for the Agency's treatment of CBI claims. As the CBI Rule does not contain any requirements to report chemical identity information to EPA, any CBI claims for chemical identity that may be made by entities without knowledge of a specific chemical identity will be governed by the specific rule that contains the reporting requirement. Moreover, the CBI Rule does not require reporting by non-confidential accession number. That requirement is contained only in certain specific reporting rules, *see*, e.g., 40 C.F.R. § 711.15(b)(3), that are not subject to challenge in this action. While the CBI Rule does establish several requirements for asserting and substantiating CBI claims for specific chemical identities, *see* 40 C.F.R. § 703.5(b)(4) (requiring responses to specific substantiation questions for

specific chemical identity CBI claims); 40 C.F.R. § 703.5(d) (requiring a submission of a generic name if the chemical identity is claimed CBI), it does not establish any reporting requirement that would generate submissions of reports containing non-confidential identifiers.

ACC's argument that EPA has "carve[d] out a new exception to the general prohibition on disclosure" is baseless. ACC Br. at 27. As explained, EPA addresses the knowledge issue when it collects the specific chemical identity information through reporting rules tailored to that collection. The language of the CBI Rule reflects that EPA retained the ability to determine, in the first instance, whether an accession number reported by a person without knowledge actually refers to the specific chemical identity. 40 C.F.R. § 703.5 ("If no such claim accompanies the submission, EPA will not recognize a confidentiality claim, and the information in or referred to in that submission may be made available to the public (e.g., by publication of specific chemical name and CASRN on the public portion of the TSCA Inventory) without further notice.").

The most effective method for addressing potential waiver of specific chemical identities by persons without knowledge is in specific reporting rules. *See supra* p.14 (explaining reporting rules). Specific reporting rules can account for the contextual nuances and relevant factors of the required reporting. For example, entities subject to chemical identity reporting in specific reporting rules might or

might not include customers of the manufacturing companies, who are less likely to be aware of the chemical identity. The Agency explained its approach in the Response to Comments. RTC at 18 ("EPA believes that the best way to address commenters' concerns is to include measures in specific TSCA reporting rules that take into account the reporting entity's potential lack of knowledge, where such measures are necessary."); *see also infra* pp. 63-64. Specific reporting rules are appropriate vehicles for addressing variables such as this to ensure adequate protection of confidential information. The CBI Rule is, therefore, entirely consistent with the disclosure provisions of 15 U.S.C. § 2613.

3. EPA's Decision to Address the Knowledge Issue in Future Reporting Rules Is Reasonable.

EPA's decision to address the knowledge issue in the context of specific reporting rules is reasonable. ACC argues that addressing these concerns in the context of specific reporting rules could result in an arbitrary outcome. ACC Br. at 36. ACC cites two cases in an attempt to support this proposition: *American Telephone and Telegraph Co. v. FCC*, 978 F.2d 727, 733 (D.C. Cir. 1992), and *Ramaprakash v. FAA*, 346 F.3d 1121 (D.C. Cir. 2003). Both cases are inapposite.

In *American Telephone and Telegraph Co.,* the Federal Communications Commission ("FCC"), when acting on a specific complaint whose outcome depended on the legality of a specific document, chose to make its decision without making a determination regarding that validity, asserting that the

Commission would decide on that validity in a future rulemaking. 978 F.2d at 729. This Court, in reviewing the FCC's decision, stated that "[t]o the extent that the Commission thought it had discretion to postpone decision to a rulemaking, it misunderstood *its role as an adjudicator*." *Am. Tel. & Tel. Co. v. FCC*, 978 F.2d at 733 (emphasis added).

In *Ramaprakash*, a suspension of a pilot's license by the Federal Aviation Administration ("FAA") was challenged in an appeal before the National Transportation Safety Board ("NTSB") as, *inter alia*, untimely based on a doctrine called the stale complaint rule. The NTSB, in a reconsideration of its previous decision finding the FAA's action timely, implied that the FAA's action might be considered untimely under the stale complaint rule but refused to make a definitive decision on the scope of the stale complaint rule, indicating that more scrutiny will be given to the application of the stale complaint rule to FAA's timeliness in the future, "depend[ing] on the specific facts of future cases and arguments." The *Ramaprakash* Court held that interpreting the stale complaint rule differently, depending on the specific facts to be arbitrary. 346 F.3d 1121, 1130.

Both *American Telephone and Telegraph Co.* and *Ramaprakash* addressed the lawfulness of a specific adjudication before the adjudicating agency where that agency declined to rule regarding an allegedly flawed legal interpretation that was key to the outcome of the adjudication. The CBI Rule, in contrast, did not involve

adjudication of any particular claims. EPA was deciding which rule—the CBI Rule or a specific reporting rule—would be the best place to address a particular issue and was not postponing a decision properly made in an adjudication to a rulemaking.

ACC's attempt to apply the principles of adjudication to a response to a comment in rulemaking is ill conceived. Unlike in *American Telephone and Telegraph Co.* and *Ramaprakash*, no specific facts are before the Agency. More apt are the cases that recognize that an agency is not required to solve every problem before it in a single rulemaking, but rather it has latitude a how to best handle related issues through rulemakings. *See, e.g.*, *Taylor v. FAA*, 895 F.3d 56, 69 (D.C. Cir. 2018); *Nat'l Postal Pol'y Council v. Postal Regul. Comm'n*, 17 F.4th 1184, 1197 (D.C. Cir. 2021), *cert. denied,* 142 S. Ct. 2868 (2022). The Agency has responded to general comments and explained how its approach addresses those comments. The Agency's response, that specific situations in specific reporting rules will be addressed when they come up, is appropriate here. The Agency wrote in its response to comments:

> Addressing the issue in the context of specific reporting rules will allow EPA to take into consideration the unique reporting context for the rule, such as the attributes of specific reporters. For example, if a reporting rule includes certain reporters who lack knowledge of specific chemical identities, EPA may consider solutions such as relieving some obligations to maintain CBI claims, shifting that obligation to a joint reporter (such as the initial manufacturer), and clarifying how the

> Agency will proceed when EPA has information demonstrating that a reporter lacks knowledge of the specific chemical identity.

RTC at 18.

EPA has adequately considered the relevant factors related to this issue. The Agency decided that addressing the knowledge issue in the context of specific reporting rules is the best way to address potential concerns about it. EPA's decision to do so is based on its rational analysis of the issue, consideration of the available options, and its experience implementing TSCA CBI requirements and is thus neither arbitrary nor capricious.

The Agency has already addressed the knowledge issue in a specific reporting rule, the proposal for which was referenced in the response to comments on the CBI Rule. *See* RTC at 18. Between receipt of the public comments on the proposed CBI Rule and publication of the final CBI Rule, EPA applied the case-by-case approach to address the knowledge issue in a specific TSCA reporting rule. EPA published the proposed PFAS reporting rule under TSCA Section 8(a)(7) on June 28, 2021, 86 Fed. Reg. 33926, and was in the process of finalizing the rule when it received public comments on the CBI Rule in June 2022. EPA subsequently published a Notice of Data Availability for the PFAS reporting rule in part to address the comments on the knowledge issue received in the CBI Rule. The Notice of Data Availability states that: "EPA seeks to clarify and add to language included in the PFAS proposed rule based on comments received in

response to the TSCA CBI Procedures proposed rule about an entity's knowledge of a specific chemical identity." 87 Fed. Reg. 72439, 72441 (Nov. 25, 2022). The Notice of Data Availability explained how the Agency anticipated addressing the knowledge issue in the final rule. The final rule stated, in relevant part, "Where EPA determines that a chemical identity was identified as a candidate for disclosure because . . . [there] was a waiver of a CBI claim by an entity that did not know the specific chemical identity, it will not move the chemical identity to the public portion of the Inventory." 88 Fed. Reg. at 70529. The Agency's action to identify and address the knowledge issue in the PFAS reporting rule demonstrates that the Agency's decision to address the knowledge issue on a case-by-case basis, in consideration of the relevant factors and reporting rules, is not arbitrary and capricious.

4. EPA Adequately Responded to Public Comments Regarding the Knowledge Issue.

EPA adequately addressed all significant comments raised during the rulemaking. ACC's argument that the Agency failed to respond to ACC's comment regarding the knowledge issue is meritless and at odds with the applicable legal standard. An agency needs to "'answer objections that on their face seem legitimate.'" *PPL Wallingford Energy LLC v. FERC*, 419 F.3d 1194, 1198 (D.C. Cir. 2005) (quoting *Canadian Ass'n of Petroleum Producers v. FERC*, 254 F. 3d 289, 299 (D.C. Cir. 2001)).

Here, EPA directly and meaningfully responded to public comments concerning persons without knowledge of a specific chemical identity waiving CBI claims for that information. For example, the Agency wrote, in the Response to Comments:

> EPA appreciates some commenters' concern that companies without knowledge of specific chemical identity (such as processors or importers) could waive a CBI claim previously asserted by another company. However, EPA believes that the best way to address commenters' concerns is to include measures in specific TSCA reporting rules that take into account the reporting entity's potential lack of knowledge, where such measures are necessary.

RTC at 18. This is clearly not a case where an agency "failed to respond to this objection in any way." *PPL Wallingford Energy*, 419 F. 3d at 1200. Rather, as this response indicates, EPA has adequately considered the public comments related to this issue. The Agency decided that addressing this issue in the context of future specific reporting rules is reasonable given the relevant factors.

CONCLUSION

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

Respectfully submitted,

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

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

I further certify that this brief complies with the type-volume limitation in the Court's November 26, 2023, Order (Doc. No. 2018960) because it contains 15,940, excluding the parts of the brief exempted under Rule 32(a)(7)(B)(iii), according to the count of Microsoft Word.

s/Phillip R. Dupré
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CERTIFICATE OF SERVICE

I hereby certify that on January 26, 2024, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the District of Columbia Circuit by using the appellate CM/ECF system.

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

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