United States Court of Appeals

FOR THE DISTRICT OF COLUMBIA CIRCUIT

Argued September 24, 2024 Decided December 20, 2024

No. 23-1166

ENVIRONMENTAL DEFENSE FUND,
PETITIONER

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY AND MICHAEL REGAN, ADMINISTRATOR OF THE UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
RESPONDENTS

AMERICAN CHEMISTRY COUNCIL,
INTERVENOR

Consolidated with 23-1204

On Petitions for Review of Final Action by the United States Environmental Protection Agency

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Samantha Liskow argued the cause for petitioner Environmental Defense Fund.

David Y. Chung argued the cause for petitioners American Chemistry Council and American Fuel & Petrochemical

Manufacturers, and intervenor American Chemistry Council. With him on the briefs were *Warren Lehrenbaum*, *Lynn T. Phan*, *Laura Gooding*, *Richard S. Moskowitz*, and *Tyler J. Kubik*.

Elbert Lin, *Matthew Z. Leopold*, and *Erica N. Peterson* were on the brief for *amici curiae* Chamber of Commerce of the United States of America and National Association of Manufacturers in support of petitioners American Chemistry Council and American Fuel & Petrochemical Manufacturers.

Phillip R. Dupré, Attorney, U.S. Department of Justice, argued the cause for respondents. With him on the brief were *Todd Kim*, Assistant Attorney General, and *Donald Sadowsky*, *Brandon Levine*, and *Stephanie Schwarz*, Attorneys, U.S. Environmental Protection Agency.

Before: WALKER and PAN, *Circuit Judges*, and EDWARDS, *Senior Circuit Judge*.

Opinion for the Court filed by *Senior Circuit Judge* EDWARDS.

EDWARDS, *Senior Circuit Judge*: The Environmental Protection Agency ("EPA") issued a final rule implementing section 2613 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2613, as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (the "Lautenberg Amendments"), Pub. L. No. 114–182, 130 Stat. 448 (2016) (codified at 15 U.S.C. § 2601 *et seq.*). The rule concerns the assertion and treatment of confidential business information ("CBI") claims for information reported to or otherwise obtained by EPA under the TSCA. *See Confidential Business Information Claims Under the Toxic Substances Control Act*,

88 Fed. Reg. 37,155 (June 7, 2023) ("CBI Rule"). This case involves two sets of challenges to the CBI Rule.

Petitioner Environmental Defense Fund ("EDF"), a non-profit environmental organization, challenges three aspects of the Rule as contrary to law and arbitrary and capricious. EDF challenges EPA's regulatory definition of health and safety study as impermissibly narrow and argues for a definition that encompasses the entirety of a study document or report. EDF also challenges EPA's decision not to require substantiation and routine agency review of pre-commercialization CBI claims after commercialization, as well as EPA's use of permissive, as opposed to mandatory, language in select provisions of the rule.

Petitioners American Chemistry Council and American Fuel and Petrochemical Manufacturers (collectively "ACC") are national trade associations that represent U.S. companies engaged in the business of chemistry or petrochemical manufacturing. They argue that the CBI Rule allows for the unlawful disclosure of information protected by section 2613(a) of the TSCA. Specifically, the TSCA prohibits EPA from publicly disclosing a specific chemical identity once a reporting entity, such as a chemical manufacturer, has satisfied the requirements for asserting and substantiating a CBI claim for that chemical identity. 15 U.S.C. § 2613(a). ACC argues that nothing in section 2613 authorizes EPA to disclose that confidential chemical identity merely because a downstream reporting entity, such as a chemical importer, has submitted information to EPA that includes only non-confidential information, such as a chemical substance's accession number. These downstream entities, according to the ACC, may lack knowledge of a substance's specific chemical identity and, thus, cannot assert and substantiate a CBI claim in accordance with the Rule's requirements.

We deny EDF's petition for review and grant ACC's petition for review. First, we hold that EPA's regulatory definition of health and safety study properly excludes matters that do not bear on the effects of a chemical substance on health or the environment. EPA's definition is consistent with the best reading of the statute and neither arbitrary nor capricious. Second, EPA is correct that the TSCA does not require a reporting entity to reassert and substantiate a CBI claim for information statutorily exempted from substantiation and agency review at the time of submission. Specifically, section 2613(c)(2)(G) exempts CBI claims for specific chemical identities asserted prior to the date on which the chemical substances are first offered for commercial distribution. These specific chemical identities remain exempt from substantiation and review until a post-commercialization CBI claim for the same chemical is received by the agency or some other statutory trigger applies. EPA's CBI Rule is consistent with this statutory exemption and provides a reasoned explanation for eliminating pre-Lautenberg regulations that could not be squared with the new exemption. Third, we hold that EPA's use of permissive language in select provisions of the Rule is consistent with the TSCA and reasonably explained. EPA has discretion to reserve its final determination of a CBI claim until the end of the 90-day statutory review period. This discretion is reflected in EPA's use of permissive language when describing its CBI claim review process. The TSCA also permits, but does not require, the public disclosure of all non-confidential information. EPA's Rule is consistent with the TSCA and reasonable in its use of permissive language with respect to information not subject to express disclosure mandates.

Fourth and last, we hold that the Rule's assertion and substantiation requirements are unlawful as applied to entities

reporting by accession numbers and without knowledge of the underlying chemical identity. As it now stands, the Rule impermissibly allows for the unlawful disclosure of protected confidential information. Reporting entities that lack knowledge of specific chemical identities are unable to assert or substantiate CBI claims for such identities. Nor do such entities reveal any confidential chemical information merely by reporting an accession number. Yet, these entities are required by the Rule to assert and substantiate CBI claims for already protected specific chemical identities. Otherwise, they waive confidentiality for the specific chemical identity, causing an upstream entity that did properly assert and substantiate a CBI claim to lose confidentiality protection. This regulatory scheme cannot be squared with the commands of the statute, which require EPA to protect from disclosure chemical identities for which CBI claims have been properly asserted.

Accordingly, we vacate EPA's rule to the extent it allows for the unlawful disclosure of confidential information.

I. BACKGROUND

A. *The Toxic Substances Control Act*

In 1976, Congress enacted the TSCA to prevent unreasonable risks of injury to health and the environment from the manufacture, processing, distribution in commerce, use and disposal of chemical substances and mixtures. *See* 15 U.S.C. §§ 2601-2697. The statute, as amended in 2016, authorizes EPA to require reporting, record-keeping, and testing, and to impose restrictions relating to chemical substances and mixtures. *See id.* §§ 2603(a), 2605, 2607(a)(1).

1. The Chemical Substance Inventory

Section 2604 of the TSCA requires that any person who intends to manufacture a new chemical substance must submit to EPA a notice of such intent at least 90 days before beginning manufacture. *Id.* § 2604(a)(1)(B). A new chemical substance is defined as any chemical not already listed on the TSCA Chemical Substance Inventory ("Inventory"), which is a comprehensive list of each chemical substance manufactured in or imported into the United States that does not qualify for an exemption or exclusion under the TSCA. *See id.* §§ 2602(11), 2607(b). As relevant here, the notice required under section 2604 is a Premanufacture Notice pursuant to 40 C.F.R. part 720. EPA must review the notice. 15 U.S.C. § 2604(a)(3). If EPA allows manufacture of the substance, then EPA will add the chemical substance to the Inventory as of the date such manufacture commences in the United States. *Id.* § 2607(b)(1).

To implement the Inventory in a manner that protects confidentiality while also assisting the public in ascertaining which chemical substances are already in commerce in the United States, EPA maintains two distinct sections of the Inventory. The public portion of the Inventory includes: (1) non-confidential chemical substances identified in part by their specific chemical identities and (2) public identifiers, such as accession numbers, for chemical substances whose identities are claimed as confidential. *See* 40 C.F.R. § 720.25(b)(1). An accession number is a random six-digit non-confidential number by which the chemical substance can later be referenced. The confidential portion of the Inventory, which is not available to the public, includes the specific chemical identities of chemical substances claimed as confidential. *Id.*

2. Reporting Rules

To obtain the information needed to compile and update the Inventory, section 2607(a) authorizes EPA to promulgate reporting rules requiring manufacturers and processors of chemical substances to maintain and submit records to EPA. *See* 15 U.S.C. § 2607(a). In 2011, EPA promulgated the Chemical Data Reporting Rule ("CDR"), formerly known as the Inventory Update Reporting Rule, which enables EPA to collect and publish information on the manufacturing, processing, and use of chemical substances on the Inventory. *TSCA Inventory Update Reporting Modifications; Chemical Data Reporting*, 76 Fed. Reg. 50,816 (Aug. 16, 2011), *amended* 76 Fed. Reg. 54,932 (Sept. 6, 2011). The CDR applies to manufacturers, including importers, that meet certain annual production volume thresholds. 40 C.F.R. § 711.8. Manufacturers must report under the CDR every four years and provide, among other things, exposure-related information associated with reportable chemical substances. *Id.* §§ 711.20, 711.15.

3. Confidentiality Claims

Subject to applicable regulations, any entity submitting information to EPA under the TSCA may claim as CBI information that they report, including the specific chemical identity of the chemical substance for which they are reporting. Specific chemical identity refers to the particular molecular identity of a chemical substance, which can encompass information on chemical structure, composition, manufacturing process, and raw materials.

Confidentiality claims are governed by TSCA section 2613. 15 U.S.C. § 2613. The Lautenberg Amendments substantially revised section 2613 to require, *inter alia*, the

assertion of confidentiality claims to protect any information submitted under the TSCA from disclosure, the substantiation of such claims, and the review of such claims by EPA. *See id.* § 2613(c)(1)(A), (c)(3), (g). Section 2613 requires EPA to protect from disclosure information, such as specific chemical identities, for which a valid CBI claim has been asserted. *Id.* § 2613(a). This general prohibition against disclosure is subject to specific limited exceptions. *Id.* § 2613(d). EPA is also required to approve, approve in part and deny in part, or deny confidentiality claims within 90 days of their assertion. *Id.* § 2613(g)(1)(A).

The requirements of assertion, substantiation, and review are subject to various statutory exemptions. Certain categories of information, such as health and safety studies, are ineligible for confidential treatment. *Id.* § 2613(b)(2). The TSCA defines "health and safety study" as:

> [A]ny 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.

Id. § 2602(8). This exemption for health and safety studies does not apply to information that discloses certain processing information or portions of a chemical mixture. *Id.* § 2613(b)(2). Such information is eligible for CBI protection. In addition, "[i]nformation 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." *Id.* § 2613(b)(1).

Furthermore, section 2613 outlines categories of information that "shall not" be subject to substantiation or agency review:

> (A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article.
>
> (B) Marketing and sales information.
>
> (C) Information identifying a supplier or customer.
>
> (D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents.
>
> (E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article.
>
> (F) Specific production or import volumes of the manufacturer or processor.
>
> (G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance, including the chemical name, molecular formula, Chemical Abstracts Service number, and other information that would identify the specific chemical substance, if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title.

Id. § 2613(c)(2), (g)(1)(C). These categories of information are not exempt, however, from section 2613(f), which outlines circumstances in which EPA may or must require entities to

reassert and substantiate their CBI claims, thereby subjecting the claims to agency review. *Id.* § 2613(f). Likewise, section 2613(e)(1)(A) articulates that "information described in subsection (c)(2)" shall be protected from disclosure "until such time as" the submitting entity withdraws the claim or EPA becomes aware that the information does not qualify for protection from disclosure. *Id.* § 2613(e)(1)(A).

B. *The EPA Confidential Business Information Rule*

Section 2613 authorizes EPA to promulgate rules on the assertion and treatment of confidentiality claims. *See id.* § 2613(c)(1)(A), (c)(3). Pursuant to this authority, EPA adopted the CBI Rule to implement section 2613 after the Lautenberg Amendments. As noted above, several provisions of the Rule are at issue in this case.

1. The Regulatory Definition of Health and Safety Study

EPA adopted a regulatory definition of "health and safety study" that excludes certain categories of information, including: (1) the name, address, or other identifying information of the submitting company, (2) the identification of the laboratory that conducted the study in cases where the laboratory is part of or closely affiliated with the submitting company, and (3) information pertaining to test substance product development, advertising, or marketing plans, or to cost and other financial data. 40 C.F.R. § 703.3(1), (4). EPA explained its approach, as follows:

> 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 [2602](8). That

> 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.

Confidential Business Information Claims Under the Toxic Substances Control Act, 87 Fed. Reg. 29,078, 29,089 (proposed May 12, 2022).

2. Exemption from Substantiation and Review

The CBI Rule exempts from substantiation and review CBI claims for specific chemical identities submitted prior to commercialization:

> A confidentiality claim for specific identity of a chemical substance, where the submission is made prior to the date on which the chemical substance whose identity is claimed as confidential is first offered for commercial distribution, is exempt from the requirement to substantiate confidentiality claims at the time of submission.

40 C.F.R. § 703.5(b)(5)(ii)(A); *see also id.* § 703.7(a)(2).

In its pre-Lautenberg regulations, EPA required entities to reassert and substantiate their pre-commercialization CBI claims after commercialization. *See* 40 C.F.R. §§ 720.85(b)(1), 720.90(b)(2) (2022). Under those regulations, the exemption granted to the CBI claim expired at the time of commercialization, requiring the submitting party to return to its previously submitted claim, reassert and substantiate it, and

subject it to agency review. Under EPA's new CBI Rule, those previously submitted claims remain exempt from substantiation and review. However, the next time an entity reports on the same chemical after the chemical has been commercialized, EPA will require the entity to assert and substantiate its CBI claim to maintain the chemical's confidentiality. *See* EPA Response to Comments at 27, 48. In addition, "[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 [2613](f)." *Id.* at 27.

In response to comments on the agency's change in position, EPA acknowledged that its pre-Lautenberg regulations required reassertion and approval. The agency explained, however, that the "final rule . . . is a simple restatement of the substantiation exemption in TSCA section [2613](c)(2)(G) for CBI claims . . . [and] [t]here is nothing in TSCA to suggest that such claims and corresponding CBI treatment automatically expire at the occurrence of a certain event." EPA Response to Comments at 48. "[R]ather, the exemption is inapplicable to *claims made after* the chemical is offered for distribution in commerce, and if the claim is revisited in the future, consistent with section [2613](f), the exemption also no longer applies." *Id.* at 48. EPA also explained that the old regulation could not be retained because it could not be squared with new requirements in the Lautenberg Amendments. *See* 88 Fed. Reg. at 37,162; EPA Response to Comments at 27. In EPA's view, the new language in section 2613, set forth in the Lautenberg Amendments, mandated its current approach.

3. Deficient Confidentiality Claims

The CBI Rule established a process for identifying and addressing "deficient confidentiality claims." 40 C.F.R. § 703.5(e). Under this provision, when a deficient claim is identified by EPA in a submission, the agency puts on hold its substantive review of the CBI claim and gives the submitter 10 business days to correct the deficiency. *Id.* § 703.5(e)(2). If the deficiency is not remedied during this window, "EPA will proceed with review of the submission and *may* deny the CBI claim(s)." *Id.* (emphasis added).

In response to comments on its use of permissive language, EPA explained 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 . . . the submitter made a persuasive argument that it was exempt from substantiation requirements)." EPA Response to Comments at 41.

4. Public Disclosure

The CBI Rule elaborated on circumstances in which non-confidential information "may" – as opposed to "must" – be disclosed. First, the Rule provides that if an entity does not include a CBI claim with its submission of information under the TSCA, then EPA will not recognize a confidentiality claim and "may" make the information available to the public. 40 C.F.R. § 703.5. Second, the Rule provides that EPA will construe an unsubstantiated claim as a waiver of the claim and "may" make the information public without any further notice to the submitter. *Id.* § 703.8(d).

5. Knowledge Issue

The CBI Rule also requires any entity submitting information under the TSCA – including entities reporting by non-confidential accession numbers and without knowledge of the underlying chemical identity – to assert CBI claims for the underlying chemical identity to maintain the chemical identity's confidentiality. *See id.* § 703.5. In the CBI Rule's preamble, EPA acknowledged that, during the rulemaking process, commenters raised a concern that, under the CBI Rule, downstream customers or processors of a specific chemical would report under TSCA by accession number and, ignorant of specific chemical identity, could inadvertently or intentionally waive the confidentiality claim and cause the substance to lose confidential status. 88 Fed. Reg. at 37,158. In response to this concern, EPA explained that it "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 . . . , the chemical identity is no longer entitled to confidential treatment and may be published on the public portion of the TSCA Inventory." *Id.* In explaining why the CBI Rule does not deal with the problem that had been identified by commenters, EPA said:

> The Agency recognizes that this issue might arise in specific contexts. However, this final rule addresses a wide variety of situations where the knowledge issue is not presented. 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 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.

Id.

C. *Procedural History*

On May 12, 2022, EPA issued its proposed CBI Rule. *See* 87 Fed. Reg. at 29,078. Petitioners EDF and ACC submitted comments. *See* EDF Comments on Proposed Rule, EPA-HQ-OPPT-2021-0419-0050 (July 11, 2022) ("EDF Comments"); ACC Comments on Proposed Rule, EPA-HQ-OPPT-2021-0419-0044 (July 11, 2022) ("ACC Comments"). EPA issued the final CBI Rule on June 7, 2023. On June 29, 2023, EDF filed a petition for review with this court. On August 4, 2023, ACC filed a petition for review with this court, which was then consolidated with EDF's challenge to the CBI Rule.

ACC was granted leave to intervene in opposition to EDF's petition for review and EDF was granted leave to intervene in opposition to ACC's petition for review. After ACC filed its opening brief, EDF decided not to file a brief in opposition to ACC's petition. The Chamber of Commerce of the United States and the National Association of Manufacturers were granted leave to participate as amici curiae in support of ACC.

II. ANALYSIS

A. *Standard of Review*

Under the Administrative Procedure Act ("APA"), we will hold unlawful and set aside final agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). In determining whether an agency's interpretation of its governing statute is contrary to law, we must exercise our "independent judgment" and "apply[] all relevant interpretive tools" to reach "the best reading of the statute." *Loper Bright Enters. v. Raimondo*, 144 S. Ct. 2244, 2262, 2266 (2024).

If an action is not contrary to law, it must be "reasonable and reasonably explained." *FCC v. Prometheus Radio Project*, 592 U.S. 414, 423 (2021); *see also Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 51-52 (1983); *Midwest Ozone Grp. v. EPA*, 61 F.4th 187, 192 (D.C. Cir. 2023).

B. *The Meaning of "Health and Safety Study"*

In the TSCA, Congress defined "health and safety study" as "any study of any effect of a chemical substance or mixture on health or the environment or on both" and excluded such studies from the information that may be claimed as confidential. 15 U.S.C. §§ 2602(8), 2613(b)(2). In the CBI Rule, EPA reasonably determined that certain information is not part of a health and safety study and therefore may be claimed as CBI. In particular, EPA interpreted "health and safety study" as the evaluation of a chemical's health and environmental effects, not an entire document containing this evaluation. EDF argues that EPA's regulatory definition of "health and safety study" is contrary to Congress's definition

of that term. EDF reads "health and safety study" as the entirety of the written report or document submitted to the EPA. We hold that EPA's construction of the term reflects the best reading of the statute.

1. The Best Reading of "Health and Safety Study"

"As with all questions of statutory interpretation, we start with the text." *Pharm. Mfg. Rsch. Servs., Inc. v. FDA*, 957 F.3d 254, 260 (D.C. Cir. 2020). Congress's word choice in section 2602(8) is instructive. Section 2602(8) defines "health and safety study" with reference to the information being studied, specifically "any effect of a chemical . . . on health or the environment." 15 U.S.C. § 2602(8). Section 2602(8) also defines "health and safety study" as "including underlying information," *i.e.*, the data on which a study is based; certain tests regarding a chemical's effects; and certain studies on, for example, the epidemiological or ecological effects of a chemical. *Id.* Taken together, these words used to define a health and safety study suggest that the term refers only to the evaluation of a chemical's health and environmental effects, not the entire document containing that evaluation. Information that is not part of an evaluation of a chemical's effects or that does not form the basis of that evaluation is not part of a health and safety study.

This interpretation of the text finds support in section 2613(b)(1), which makes clear that CBI "protected from disclosure . . . does not lose its protection" when "mixed with information . . . not protected from disclosure." *Id.* § 2613(b)(1). The TSCA thus recognizes that a single document can contain a mix of both information that is exempt from the disclosure protection of section 2613(a) and information that is covered by that protection. A study document, for example, may contain protected information –

like the company that manufactures a chemical – and unprotected information, like an evaluation of that chemical's effects. The former does not lose its protection by appearing in the same document as the latter.

A limited definition of health and safety study also gives effect to the purpose of the statute. With section 2613, Congress sought to strike "a balance between protecting trade secrets . . . and broadening access to information." S. Rep. No. 114-67, at 21 (2015). The best reading of health and safety study allows the public to access data and analysis regarding a chemical's effects, while protecting other sensitive information that happens to be in the study document. A definition of health and safety study that is limited to the evaluation of a chemical's effects best strikes the balance sought by Congress.

2. EPA's Regulatory Definition

EPA's regulatory definition is consistent with the best reading of TSCA's definition of "health and safety study." None of the information EPA identified as excluded from a "health and safety study" is part of an evaluation of a chemical's effects, nor does it constitute the information underlying that evaluation. *See* 40 C.F.R. § 703.3. Specifically, the name of the submitting company, the name of the testing laboratory, and product information (e.g., financial or marketing information) do not pertain to the methods used, the results reported, or the reasoning provided by an evaluation of a chemical's effect, nor the data on which that evaluation is based. Their exclusion from EPA's regulatory definition of "health and safety study" is thus consistent with the TSCA.

EPA also provided a reasoned basis for these exclusions. In response to comments on the relevance and utility of the excluded information, EPA explained that "[t]hese existing

carveouts . . . permit[] 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." EPA Response to Comments at 12. This explanation is entirely consistent with the purpose of the Lautenberg Amendments, which was to strike "a balance between protecting . . . sensitive commercial and financial information and broadening access to information" to better inform the decisions made about chemicals by various levels of government, companies, and the general public. S. Rep. No. 114-67, at 21 (2015). EPA's exclusions are thus consistent not only with the statutory text but also with the statutory purpose. Having addressed the need for a balanced approach, EPA need not respond to every comment on the value of the withheld information to the public. *See U.S. Satellite Broad. Co. v. FCC*, 740 F.2d 1177, 1188 (D.C. Cir. 1984) ("[A]n agency need not respond to every comment so long as it responds in a reasoned manner to significant comments received.").

EPA's approach is also consistent with its past practice. The agency's longstanding position is that certain, limited categories of information in a health and safety study report, beyond the information identified in section 2613(b)(2), might be entitled to confidential treatment. Since at least the early 1980s, EPA has interpreted "health and safety study" to exclude information, such as company name or address, financial statistics, or product codes, deemed irrelevant to any health or environmental effect of a chemical. *See* 40 C.F.R. § 716.16(c)(2) (1984). When Congress enacted the Lautenberg Amendments, it did not substantively change the provision of section 2613 dealing with health and safety studies, which suggests that Congress did not intend to undermine EPA's longstanding approach. *See NLRB v. Bell Aerospace Co.*, 416 U.S. 267, 275 (1974) ("[W]here Congress has re-enacted the statute without pertinent change . . . congressional failure to

revise or repeal the agency's interpretation is persuasive evidence that the interpretation is the one intended by Congress.").

Thus, EPA's interpretation of health and safety study is consistent with the best reading of the statute, reasonably explained, and consistent with past practice.

3. EDF's Arguments to the Contrary

Still, EDF argues that "health and safety study" refers to the entirety of the written report or document submitted to EPA. EDF primarily relies on the ordinary meaning of the word "study." According to *Merriam-Webster*, "study" can mean either (1) "a careful examination or analysis of a phenomenon, development, or question" or (2) "the published report of such a study." *Study*, MERRIAM-WEBSTER, https://perma.cc/P4KK-F6YN (last visited Dec. 3, 2024). EDF primarily relies on the latter, contending that Congress defined health and safety study expansively without any exclusions for pieces of information found within the study documents. Statutory definitions, however, "often 'giv[e] ordinary words a limited or artificial meaning.'" *Telematch, Inc. v. U.S. Dep't of Agric.*, 45 F.4th 343, 350 (D.C. Cir. 2022) (bracket in the source text). Here, the statutory definition's emphasis on what is being examined or analyzed serves to limit the meaning of "health and safety study" to the evaluation of a chemical's effects and the data on which that evaluation is based. Accordingly, the CBI Rule distinguished a "study" from a "study document," and explained that a "study document" often includes extra information that is not part of a "health and safety study," as that term is used in the TSCA. *See* 88 Fed. Reg. at 37,157.

EDF's reading is also difficult to reconcile with section 2613(b)(1)'s recognition that protected and non-protected

information will often be mixed. EDF attempts to square the circle by pointing to section 2613(b)(2), which provides that certain health and safety study information is nevertheless protected from disclosure if it qualifies as CBI, notwithstanding section 2613(b)(2)'s rule that information from such studies is generally not protected. In particular, section 2613(b)(2) protects "any information, including formulas . . . , that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture." According to EDF, section 2613(b)(1) merely serves to ensure that, with respect to a health and safety study, the information protected by section 2613(b)(2) remains protected even when it is in an otherwise non-protected health and safety study. But EDF's reading would render (b)(1) superfluous, as (b)(2) alone would be sufficient to indicate that formulas, for example, are to be redacted, notwithstanding the fact that they appear with non-protected parts of such a study. Section 2613(b)(1) must be read to apply to some other protected information mixed with a not protected health and safety study.

EDF also argues that EPA's regulatory definition violates TSCA by establishing additional "carveouts" to section 2613(b)(2) beyond the two narrow exceptions identified in that provision. However, section 2613(b)(2)'s exceptions relate to information that is part of a health and safety study because that information (e.g., "formulas . . . of a chemical substance") pertains to the evaluation of a chemical's effects. EPA's regulatory definition does not create exceptions for information that is part of a health and safety study; rather, it clarifies that certain information is not part of such a study because it does not pertain to such an evaluation.

Lastly, EDF argues that EPA's regulatory exclusions will make it more difficult for the public to understand a chemical's uses and exposures, as well as the strength and reliability of the studies. While the excluded information may be relevant to a chemical's effects generally, it is not information from a particular study's evaluation of a chemical's effects on health or the environment, nor is it information underlying that evaluation. Product information, for example, may provide clues about a chemical's potential real-world effects, but it does not constitute information from a specific study's evaluation of the chemical's effects on, for example, the mortality rates of water fleas. Because the excluded information does not pertain to a particular evaluation of a chemical's effects or the underlying information, EPA is correct that the information is not part of a "health and safety study." In other words, the mere fact that a member of the public may find certain information in a study document useful does not cause that information to become part of an evaluation of a chemical's effects.

C. *Exemption for Pre-Commercialization CBI Claims*

In general, the TSCA requires entities submitting information under the TSCA to substantiate any claim for CBI. EPA then reviews these claims. Section 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 agency review. EDF and EPA do not dispute that pursuant to section 2613(c)(2)(G), CBI claims for chemical identities made "prior to" commercialization are not subject to substantiation and routine review. The parties disagree, however, as to the duration of this exemption.

Under EPA's interpretation, the pre-commercialization CBI claim remains exempt from substantiation and routine review unless and until a post-commercialization CBI claim for

that same chemical is received or some other statutory trigger applies. Under EDF's interpretation, the submitter must reassert and substantiate, and EPA must review, the CBI claim for chemical identity when the chemical is later offered for commercial distribution. EDF also argues that EPA acted arbitrarily and capriciously in reversing longstanding regulations requiring post-commercialization substantiation and review of pre-commercialization claims. We reject both of EDF's arguments.

First, EPA's interpretation is consistent with the best reading of the statute. Section 2613(c)(2) contains the statutory mandate that a CBI claim for information described in subsections (A) through (G) "shall not be subject to substantiation requirements." This mandate does not contain durational language limiting the exemption to a discrete period of time. Instead, the use of "shall not" is unequivocal: These categories of information are exempt from substantiation.

Congress does impose a durational limit on subsection (G), which describes the category of information at issue. In subsection (G), the phrase "prior to" is best read to modify the category of information to be exempt from substantiation: A CBI claim for a specific chemical identity submitted "[p]rior to the date on which the chemical substance is first offered for commercial distribution" is exempt from substantiation. Appearing nowhere in the mandate itself, this language is relevant only to defining the category of information to be exempt from substantiation, not the duration of the exemption.

Although the mandate in section 2613(c)(2) does not contain a durational limit, it is not unconditional. Section 2613(e)(1)(A) requires EPA to protect from disclosure the information described in subsection (c)(2) "until such time as" the submitter withdraws the claim or EPA learns that the

information "does not qualify for protection from disclosure." 15 U.S.C. § 2613(e)(1)(A). In addition, the categories of information described in subsection (A) through (G) are "[s]ubject to subsection (f)," which outlines specific circumstances in which the EPA must or may require reassertion and substantiation. *Id.* § 2613(f). For example, EPA is required to ask submitting entities "to reassert and substantiate" their CBI claims if necessary for the EPA resolve a Freedom of Information Act request for the exempted information. *Id.* § 2613(f)(2)(A). Noticeably absent from the enumerated list of triggers is commencement of commercial distribution. Section 2613(f) does not require the EPA to demand entities to reassert or substantiate their CBI claims for specific chemical identities solely because of commercialization. Instead, after a chemical substance is in commercial distribution, the next time an entity reports on that substance's specific chemical identity, the entity will be required to substantiate a CBI claim and EPA will review that claim pursuant to section 2613.

Second, EPA did not act arbitrarily or capriciously in eliminating its pre-Lautenberg regulatory provisions. Those prior regulations did require entities to reassert and substantiate their pre-commercialization CBI claims after commercialization. *See* 40 C.F.R. §§ 720.85(b)(1), 720.90(b)(2) (2022). However, "[a]gencies are free to change their existing policies as long as they provide a reasoned explanation for the change." *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). EPA reasonably explained that its change in position was in response to new language in the Lautenberg Amendments exempting pre-commercialization claims from substantiation and review. EPA found that the prior regulations could not be squared with the statutory exemption. *See* EPA Response to Comments at 48.

D. *EPA's Duties Under the TSCA*

At several points in the CBI Rule, EPA uses permissive language to describe its duties as to deficient CBI claims and non-confidential information. EDF challenges these provisions as unlawful, arguing that EPA improperly treats as discretionary its mandatory duties under the TSCA. EDF also argues that EPA replaced previous mandatory provisions with discretionary provisions without adequate explanation. Both arguments fail. The provisions at issue are consistent with the best reading of the statutory text, and EPA's use of permissive language was reasonably explained.

1. The CBI Rule's Treatment of Deficient CBI Claims

Although the TSCA does not give EPA discretion to approve a deficient CBI claim, it does allow EPA to reserve its final determination of a CBI claim until the end of the 90-day review period. *See* 15 U.S.C. § 2613(g)(1)(A). Consistent with the statute, the CBI Rule articulates that if a deficiency is not remedied during the correction period – which lasts for 10 days, during which review of the underlying CBI claim is suspended – then EPA will proceed with review of the submission and *may* deny the CBI claim. 40 C.F.R. § 703.5(e)(2) (emphasis added). This "may deny" language refers to the possibility that after the 10-day correction window and before the end of the 90-day review period, intervening factors may arise that affect EPA's confidentiality determination. Contrary to EDF's contention, this language does not grant EPA discretion to approve a deficient CBI claim.

A situation might arise, for example, where EPA receives a CBI claim that it initially determines to be improperly substantiated. EPA will suspend the underlying review for 10 business days to allow for a correction. If the submitter has not

made the correction by the end of the 10-day period, the claim remains deficient, but the 90-day statutory period may not have expired. During the time remaining in the 90-day review period, EPA may determine that substantiation *is* adequate and, accordingly, approve the claim. Or it might determine that an exception to substantiation and review applies and, therefore, take no action on the claim. *See* 15 U.S.C. § 2613(g), (c)(2). Conversely, a deficient claim that is corrected during the 10-day window may nevertheless be deemed deficient upon further inspection prior to the conclusion of review. Requiring EPA to deny the deficient claim after the 10-day correction period would short-circuit this process and deny EPA the benefit of its statutorily authorized 90-day review period. Of course, if the end of the 10-day period coincides with the end of the 90-day statutory review period and the claim remains deficient, then EPA must deny the claim.

EPA also reasonably explained its intentional use of this permissive language. *See* EPA Response to Comments at 41 ("[T]he 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 . . . the submitter made a persuasive argument that it was exempt from substantiation requirements).").

2. The CBI Rule's Treatment of Non-Confidential Information

The best reading of the TSCA is that it permits, but does not require, the disclosure of all information that falls outside of the section 2613(a) prohibition on disclosure. Importantly, the TSCA does not contain a general requirement of disclosure for all non-confidential information. Instead, where Congress does require information to be disclosed, it states so expressly. For example, section 2607(b)(7) requires EPA to disclose

chemical identities not subject to valid CBI claims. *See* 15 U.S.C. § 2607(b)(7). In addition, section 2625(j) lists five categories of information, such as risk evaluation studies, that the Administrator "shall make available to the public" consistent with the requirements of section 2613. *See id.* § 2625(j). Such provisions suggest that, in the absence of an express mandate, EPA is not subject to a mandatory duty to disclose. *See also id.* § 2613(d) (listing information that "shall be disclosed" in specific circumstances). Thus, EPA is under no obligation to generally disclose all non-confidential information when not required to under one of the statute's express mandates.

EPA's use of permissive language in two provisions of the CBI Rule is consistent with the statute's express disclosure mandates. *See* 40 C.F.R. §§ 703.8(d) ("[I]n the case of any unsubstantiated claim, EPA will construe this as a waiver of the claim and *may* make the information public without any further notice to the submitter."), 703.5 ("If no [CBI] 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.") (emphases added). The TSCA does not require any and all information not accompanied by a CBI claim, or accompanied by an unsubstantiated CBI claim, to become publicly available. Rather, such information shall be made available to the public when required by the specific disclosure mandates, or when requested by the public. *See* EPA Response to Comments at 41 (explaining that the use of permissive language "is not intended to suggest that disclosure is in doubt *when the information is requested*").

EPA's use of discretionary language is neither arbitrary nor capricious. In its pre-Lautenberg regulations, EPA did require the automatic and immediate disclosure of information that

failed to meet statutory requirements for confidentiality. *See* 40 C.F.R. §§ 716.55(c), 704.7(b) (2022) (repealed 2023). EPA, however, reasonably explained its change in position in response to comments: The use of "may" when discussing public disclosure is intended "to provide EPA with discretion and flexibility on the timing for proactively or unilaterally disclosing data, particularly when there is little or no evident demand for the information." EPA Response to Comments at 41. The prior regulations also could not be retained because they did not "fully implement the new requirements under section [2613] and ha[d] a good deal of variation in their requirements." EPA Response to Comments at 46.

Having properly explained why it eliminated the pre-Lautenberg regulations, as well as why it has decided to use permissive language in its new regulations, EPA has met the standard for reasoned decision-making. *See Encino Motorcars*, 579 U.S. at 221 ("Agencies are free to change their existing policies as long as they provide a reasoned explanation for the change.").

E. *The CBI Rule As Applied to Entities Reporting by Accession Number and Without Knowledge*

Under the CBI Rule, a company with no knowledge of the specific chemical identity of a particular chemical substance – such as a downstream customer that only knows the substance's generic chemical name and non-confidential accession number – could waive CBI protection for the specific chemical identity simply by submitting a report to EPA that identifies the substance by its non-confidential referents. This is the case even where the downstream customer does not possess any confidential information and, thus, is not in a position to assert, much less substantiate, a CBI claim. The CBI Rule is unlawful to the extent it allows such waiver to occur.

The existing regulatory regime requires downstream users of a chemical substance, such as a chemical processor or importer, to report information to the EPA. These entities, unlike chemical manufacturers, do not always have knowledge of a chemical substance's specific chemical identity. Accordingly, EPA allows these entities to identify the chemical substance for which they are reporting by its non-confidential generic name or accession number, as opposed to its confidential chemical identity. *See* 40 C.F.R. part 711; *see also* 40 C.F.R. § 711.15. Yet, despite these entities' lack of knowledge on the matter, the CBI Rule requires these entities to assert and substantiate CBI claims for specific chemical identities when reporting to the EPA, even when their reports contain only non-confidential chemical information. Otherwise, EPA deems confidentiality for the specific chemical identity waived, and EPA may make the chemical identity publicly available. In other words, an entity's lack of knowledge is no defense to the CBI Rule's assertion and substantiation requirements. This regulatory scheme cannot be squared with the commands of the statute.

Once an entity has satisfied the requirements for asserting and substantiating a confidentiality claim for a specific chemical identity, the TSCA prohibits EPA from disclosing that chemical identity except in narrow circumstances enumerated in the statute. *See* 15 U.S.C. § 2613(a), (d)-(e). The submission of a report that refers to a chemical substance by only its non-confidential accession number is not among those circumstances. Indeed, it is not clear that an entity that reports using a non-confidential accession number has submitted confidential information that would trigger the statute's CBI claim requirements in the first place. Section 2613(c)(1)(A) requires a person seeking to protect from disclosure "any information that person submits" under the TSCA to assert a

confidentiality claim. It is a stretch to say that an entity that is allowed to report by an accession number is submitting information on the underlying specific chemical identity. They merely submit information as to the chemical substance, not its specific molecular identity. Accordingly, such entities are not required to assert CBI claims for specific chemical identities when merely reporting on a chemical substance by reference to its generic name or accession number.

A reporting entity's failure to assert and substantiate a CBI claim for a specific chemical identity due to its lack of knowledge of that identity is also not a statutory ground for disclosure. Indeed, it is not clear how a downstream customer who lacks knowledge can verify that the specific chemical identity is not readily discoverable through reverse engineering, as required for CBI claim assertion. *Id.* § 2613(c)(1)(B)(iv). The CBI Rule, as applied to these entities, allows for the inadvertent waiver of confidentiality to occur, thereby jeopardizing the confidentiality protections established by upstream entities. Moreover, as the parties acknowledged during oral argument, a downstream company may have no interest in protecting the confidentiality of another company's trade secrets – and indeed, may have an interest in those secrets becoming public. The CBI Rule would allow downstream entities without knowledge to inadvertently or intentionally waive a competitor's CBI claim.

EPA acknowledges the genuine concern posed by this knowledge issue and yet declines to address it in the CBI Rule. It argues that the issue would be best addressed in later rules that contain specifically tailored reporting requirements. This argument is unpersuasive because the CBI Rule, as it currently stands, allows for unauthorized disclosures of confidential information, making it contrary to law. EPA cannot wait to address this unlawfulness at a later point in time.

It is also of no avail for the EPA to argue that it has long required all entities, regardless of their knowledge, to assert and substantiate CBI claims when reporting only by accession number. ACC disputes EPA's characterization of the agency's past practice, but even if we accepted EPA's characterization, the fact that the practice is longstanding cannot render it lawful.

To conclude, the CBI Rule is unlawful to the extent it allows a downstream entity reporting on a chemical substance by accession number and without knowledge of the underlying specific chemical identity to waive confidentiality for that specific chemical identity. Because we address ACC's petition on statutory grounds, we decline to reach ACC's alternative arguments that the EPA's approach to the knowledge issue is arbitrary and capricious.

III. CONCLUSION

For the reasons set forth above, we grant ACC's petition for review and deny EDF's petition for review. As indicated in the foregoing opinion, the CBI Rule fails review in only one respect: The Rule is unlawful insofar as it requires entities reporting by non-confidential accession numbers and without knowledge of the underlying chemical identity to assert CBI claims for the underlying chemical identity in order to maintain the chemical identity's confidentiality. 40 C.F.R. § 703.5. Neither the TSCA nor good reason justifies these terms of the CBI Rule. We hereby vacate these requirements under the CBI Rule.