

No. 23-1166 & 23-1204

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

AMERICAN CHEMISTRY COUNCIL, ET AL.,

Petitioners,

v.

U.S. ENVIRONMENTAL PROTECTION AGENCY,

Respondent.

ON PETITIONS FOR REVIEW OF FINAL AGENCY ACTION
OF THE ENVIRONMENTAL PROTECTION AGENCY

**FINAL BRIEF OF PETITIONERS AMERICAN CHEMISTRY COUNCIL
AND AMERICAN FUEL & PETROCHEMICAL MANUFACTURERS**

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CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES**A. Parties, intervenors, and amici**Petitioners:

American Chemistry Council; American (23-1204)
Fuel & Petrochemical Manufacturers

Environmental Defense Fund (23-1166)

Respondent:

Environmental Protection Agency

Respondent-Intervenors:

Environmental Defense Fund (23-1204)

American Chemistry Council (23-1166)

Amici:

U.S. Chamber of Commerce (23-1204)

B. Rulings under review

The agency action under review is EPA's final rule, entitled Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 37,155 (June 7, 2023), which this Brief identifies throughout as the "Final Rule."

C. Related cases

The consolidated cases have not been reviewed by this or any other Court.

CORPORATE DISCLOSURE STATEMENT

In accordance with Federal Rule of Appellate Procedure 26.1 and Circuit Rule 26.1, Petitioners provide the following disclosures:

American Chemistry Council (“ACC”) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people’s lives better, healthier, and safer. ACC is committed to improved environmental, health, and safety performance through common sense advocacy designed to address major public policy issues, and health and environmental research and product testing. The business of chemistry is a \$639 billion enterprise and a key element of the nation’s economy. It is among the nation’s largest exporters, accounting for ten percent of all U.S. goods exported. ACC has no parent company, and no publicly held company has a 10% or greater ownership interest in ACC. ACC is a “trade association” under Circuit Rule 26.1.

American Fuel & Petrochemical Manufacturers (“AFPM”) is a national trade association whose members comprise most U.S. refining and petrochemical manufacturing capacity. AFPM has no parent companies, and no publicly held company has a 10% or greater ownership interest in AFPM. AFPM is a “trade association” under Circuit Rule 26.1 and operates for the purpose of promoting the general commercial, professional, legislative, or other interests of its memberships.

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GLOSSARY

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|------------------------|--|
| ACC | American Chemistry Council |
| AFPM | American Fuel & Petrochemical Manufacturers |
| CBI | Confidential Business Information |
| CDR | Chemical Data Reporting |
| EPA | Environmental Protection Agency |
| Final Rule | Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA), 88 Fed. Reg. 37,155 (June 7, 2023) |
| FOIA | Freedom of Information Act |
| Inventory | Toxic Substances Control Act Chemical Substance Inventory |
| Inventory Reset Rule | TSCA Inventory Notification (Active-Inactive) Requirements, 82 Fed. Reg. 37,520-02 (Aug. 11, 2017) |
| JA | Joint Appendix |
| Notice of Commencement | Notice of Commencement of Manufacture or Import |
| TSCA | Toxic Substances Control Act |

JURISDICTION

On August 4, 2023, Petitioners filed a timely petition for review of the final rule of the Environmental Protection Agency (“EPA” or “Agency”), entitled Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA), JA001-JA020 (88 Fed. Reg. 37,155 (June 7, 2023)). This Court has jurisdiction pursuant to 15 U.S.C. § 2618(a).

STATEMENT OF ISSUES

1. Whether the Final Rule, which governs the assertion and treatment of confidential business information claims for information reported to or otherwise obtained by EPA under the Toxic Substances Control Act (“TSCA”), is contrary to TSCA, unreasonable, arbitrary and capricious, an abuse of discretion, without adequate explanation of its reasoning, or otherwise not in accordance with law.

STATUTES AND REGULATIONS

The Addendum provides pertinent statutes and regulations.

STATEMENT OF THE CASE

In implementing TSCA, EPA may require chemical manufacturers to report confidential information to the Agency. The statute prohibits EPA from disclosing that information except in certain enumerated circumstances. This case is about ensuring the protection of highly confidential and commercially valuable chemical identities reported to EPA under TSCA.

I. TSCA Statutory Provisions

In 1976, Congress enacted TSCA to establish a national program to regulate the manufacturing, processing, distribution, and use of chemical substances and mixtures in the United States to prevent unreasonable risks to health or the environment. *See* 15 U.S.C. §§ 2601-97. The statute, as amended in 2016 by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (“Lautenberg Act”),¹ authorizes EPA to require reporting, record-keeping and testing, and to impose restrictions relating to chemical substances and mixtures. *See id.* § 2607(a)(1)(A), (B).

Section 5 of 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. 15 U.S.C. § 2604(a)(1). “Manufacture” means to “import . . . , produce, or manufacture.” *Id.* § 2602(9). 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 U.S. that does not qualify for an exemption or exclusion under TSCA. *Id.* § 2602(11). The notice typically required under Section 5 is a Premanufacture Notice under 40 C.F.R. part 720. After EPA completes its review of a Premanufacture Notice, the submitter may initiate commercial

¹ Pub. L. No. 114-182 (June 22, 2016).

manufacture of the substance provided that the person files with EPA a Notice of Commencement of Manufacture or Import (“Notice of Commencement”) pursuant to 40 C.F.R. § 720.102. Upon receipt of the Notice of Commencement, EPA must add the chemical substance to the Inventory. 40 C.F.R. § 720.25; 15 U.S.C. § 2607(b).

Section 8(b) of TSCA requires EPA to compile, keep current, and publish the Inventory. 15 U.S.C. § 2607(b). The Inventory must include chemical substances reported under a prior Inventory compilation and each chemical substance for which a Premanufacture Notice has been submitted and manufacturing has commenced. *Id.* § 2607(b)(1). The Inventory includes two portions: (1) the public portion of the Inventory, which contains no confidential information and publicly discloses all chemical substances for which chemical identity has not been claimed confidential by providing their specific chemical identities and Chemical Abstracts Service numbers; and (2) the confidential portion of the Inventory, which includes the specific chemical identities and Chemical Abstracts Service numbers of substances with confidential identities, but is visible only to EPA. A redacted version of the confidential portion of the Inventory can be accessed by the public, but this redacted version does not include specific chemical identities or Chemical Abstracts Service numbers and instead identifies confidential chemicals only by EPA-assigned, six-digit accession numbers and generic chemical names in place of specific chemical

identities. At this time, there are over 17,000 chemical identities listed on the confidential portion of the Inventory. *See* U.S. EPA, August 2023 TSCA Inventory.² EPA refers to the public version of the Inventory together with the redacted version of the confidential Inventory as the “non-confidential Inventory.”³

An entity planning to manufacture a chemical substance already listed on the Inventory is not required to submit any information to EPA before commencing manufacture. If an entity is unsure whether the specific substance it intends to manufacture is already on the confidential portion of the Inventory, that entity may submit an inquiry known as a Bona Fide Intent to Manufacture Notice to EPA. In this notice, the entity must provide the information required under 40 C.F.R. § 720.25 to demonstrate a bona fide intent to manufacture or import a chemical substance for a commercial purpose. If EPA determines the entity has demonstrated a bona fide intent, EPA must inform the submitter whether the chemical substance is listed on the confidential portion of the Inventory. 40 C.F.R. § 720.25(b)(5).

To obtain information needed to compile and update the Inventory, Section 8(a) authorizes EPA to promulgate rules under which manufacturers and processors

² Available at <https://www.epa.gov/tsca-inventory/how-access-tsca-inventory> (explaining that Table PMNACC_082023 “[c]ontains non-confidential data for the confidential chemical substance listings, as identified by EPA accession number and generic chemical name”) (last visited Nov. 6, 2023).

³ *Id.*

of chemical substances must maintain and submit records to EPA. In 2011, EPA promulgated the Chemical Data Reporting rule (“CDR”)—formerly known as the Inventory Update Rule—which enables EPA to collect and publish information on the manufacturing, processing, and use of chemical substances on the Inventory. 76 Fed. Reg. 50,816 (Aug. 16, 2011). The CDR requires manufacturers to report on a chemical substance if the manufacturer meets 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, company and site information, and exposure-related information associated with reportable chemical substances such as the physical form and maximum concentration of the chemical substance and the number of potentially exposed workers. 40 C.F.R. § 711.20; *id.* § 711.15.

Any entity submitting information to EPA under TSCA may claim that the specific chemical identity of the chemical substance for which they are reporting is confidential business information (“CBI”), so long as the chemical substance is on the confidential portion of the Inventory.⁴ *E.g.*, 40 C.F.R. § 703.5. Specific chemical identity refers to the “particular molecular identity” of a chemical substance, *see* 15 U.S.C. § 2602(2), which can encompass information on chemical structure,

⁴ Even if a chemical substance is on the public inventory, other data elements such as company name or uses can still be claimed as CBI.

composition, manufacturing process, and raw materials.⁵ Not surprisingly, specific chemical identities can be highly confidential trade secrets.⁶ Congress plainly recognized that fact and thus, the statute repeatedly references maintaining claims for protection against disclosure of specific chemical identities. *E.g.*, 15 U.S.C. §§ 2607(b)(4)(B), 2607(b)(4)(C), 2607(b)(5)(B), 2613(c)(1)(C), 2613(c)(4), 2613(g)(4).

Confidentiality claims are governed by TSCA Section 14, 15 U.S.C. § 2613, and EPA’s regulations at 40 C.F.R. part 703. TSCA generally prohibits EPA from disclosing information that qualifies as “trade secrets and commercial or financial information obtained from a person and privileged or confidential” under 5 U.S.C. § 552(b)(4), except as specifically provided in TSCA Section 14. *See* 15 U.S.C. § 2613(a).

To assert a claim of confidentiality, a person must include a statement that they have—

⁵ *Regulation of New Chemicals, Protection of Confidential Business Information, and Innovation: Hearing Before the H. Comm. on Energy & Commerce, Subcomm. On Env’t & the Economy, 113th Cong. 135-51 (July 11, 2013) (Letter from M. Walls to Hon. J. Shimkus with Responses of ACC to Questions for the Record at 2 (Aug. 14, 2013)) (“ACC Response”), available at <https://www.gpo.gov/fdsys/pkg/CHRG-113hhr86392/pdf/CHRG-113hhr86392.pdf>.*

⁶ *See id.*, 113th Cong. 8-22 (Testimony of Craig Morrison on Behalf of ACC Regarding Sections 5 & 14 of the Toxic Substances Control Act, at 3) (“Morrison Testimony”), available at <https://www.gpo.gov/fdsys/pkg/CHRG-113hhr86392/pdf/CHRG-113hhr86392.pdf>.

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

15 U.S.C. § 2613(c)(1)(B). This four-part statement reflects the substantive requirements for protection from disclosure under Exemption 4 of the Freedom of Information Act (“FOIA”), 5 U.S.C. § 552(b)(4).

In addition, where a confidentiality claim is made for chemical identity, the claim must include a “structurally descriptive generic name” for the chemical substance that EPA may disclose to the public. 15 U.S.C. § 2613(c)(1)(C). TSCA requires EPA to develop guidance regarding the creation of such structurally descriptive generic names. *Id.* § 2613(c)(4). Additionally, EPA must also “develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term.” 15 U.S.C. § 2613(g)(4)(A)(i).

II. Factual Background

Each year, companies invest billions of dollars in research and development to bring chemicals to the U.S. market, and the ability to protect confidential information from disclosure is a critical element in fostering innovation.⁷ In particular, “[m]uch of the innovation in chemistry depends on protection of confidential chemical identities, which are among the most valuable intellectual property in the chemical industry.”⁸ Chemical identities “can provide information on chemical structure, composition, formulation, manufacturing process, raw materials,” and they “disclose information that puts significant investment in new product development at risk to competitors.”⁹ Companies would be reluctant to continue investing billions of dollars “if their ‘secret ingredient[s]’ would be freely available to any foreign or domestic competitor once the chemical is on the market.”¹⁰

Importantly, protecting specific chemical identities from disclosure where manufacturers have properly asserted and substantiated CBI claims does not mean that information related to the underlying chemical substance escapes scrutiny.

⁷ See Morrison Testimony, *supra*, at 3 & 10.

⁸ *Id.* at 10.

⁹ ACC Response, *supra*, at 2.

¹⁰ *Id.*

Starting with the obvious, EPA has access to all information reported under TSCA, whether confidential or not. TSCA Section 14 authorizes EPA to disclose confidential information under limited circumstances, such as when disclosure is necessary to protect against an unreasonable risk of injury to health and the environment. *See* 15 U.S.C. § 2613(d). Furthermore, because of the statutory requirement to provide structurally descriptive generic names for any substance where the specific chemical identity is the subject of a properly substantiated CBI claim, the public can access relevant health and safety studies for chemical substances whose identities are confidential. In fact, “ACC’s analysis has indicated that the generic names actually provide *greater access* to relevant health and safety studies and information on substances than the specific chemical name or [Chemical Abstracts Services] number.”¹¹ This is because “[g]eneric names all link to the scientific literature on similarly structured substances,” whereas “there may not be published scientific literature on the specific chemical substance, particularly in the case of new or recently developed chemicals.”¹² Finally, EPA provides an easy mechanism for referencing substances whose identities are confidential by assigning those substances otherwise random six-digit “accession numbers” when those substances are first added to the confidential portion of the Inventory.

¹¹ Morrison Testimony, *supra*, at 12 (emphasis added).

¹² *Id.*

Chemical substances listed on the confidential portion of the Inventory remain subject to reporting requirements, such as CDR, but it is often the case that reporting entities will lack knowledge of the specific chemical identity of a particular substance. Pursuant to the CDR, downstream manufacturers (including importers) who possess only non-confidential information related to the identity of a reportable chemical substance—namely, generic name and EPA-assigned six-digit accession number—must nonetheless report that chemical substance by its accession number to fulfill their reporting obligations. *See* 40 C.F.R. part 711. In such instances, the submitter is not in a position to assert or substantiate a CBI claim for the substance’s confidential chemical identity, because the submitter is unaware of the confidential chemical identity.

III. EPA Promulgates the Final Rule.

On May 12, 2022, EPA proposed a rule to implement the new provisions required by the Lautenberg Act regarding the assertion, substantiation, and review of CBI claims. *See generally* JA021-JA045 (87 Fed. Reg. 29,078 (May 12, 2022)). In relevant part, the proposed rule required that confidentiality claims be asserted and substantiated at the time of submission. *Id.* at 29,081-82 (codified at 40 C.F.R. § 703.5). If no such claim is made, EPA could disclose the information to the public without further notice. *Id.* The proposed rule “further clarif[ied]” that where a TSCA submission identifies a chemical substance listed on the confidential portion of the

Inventory but does not assert a confidentiality claim for the specific chemical identity, such chemical identity “would no longer be eligible for confidential treatment on the TSCA Inventory.” *Id.* As a result, EPA would update the Inventory to “publicly list the specific chemical name” without further notice “to any person who may have made a CBI claim for this substance[.]” *Id.*

Under the proposed 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 a non-confidential, six-digit “accession number” that EPA has assigned to the substance—could waive the underlying CBI protection for the confidential specific chemical identity simply by submitting a report to EPA that identifies the substance only by referring to its non-confidential generic name and accession number. *See id.* That is the case even though the downstream customer does not possess any confidential information (*i.e.*, the specific chemical identity) and thus, is not in a position to assert, much less substantiate, a CBI claim.

This scenario frequently occurs where Company A, a U.S.-based company, manufactures a confidential chemical substance, for which a CBI claim has been properly asserted and substantiated, and sells it to Company B, a foreign manufacturer. Company B then processes the substance for Company C, who imports the substance into the U.S. In many cases, Company B and Company C may

know the chemical substance's accession number but not the underlying confidential chemical identity. Company C is nonetheless required to report under the CDR using the chemical substance's accession number. Under the proposed rule, if Company C does not assert a CBI claim for the specific chemical identity (which Company C does not know), Company C's report would waive CBI protection for the chemical identity, and EPA may move the chemical substance to the public portion of the Inventory without further notice to any party.

Petitioners submitted comments on the proposed rule that, among other things, raised concerns regarding EPA's interpretation that it would no longer recognize claims to protect specific chemical identities as CBI in cases where downstream customers submit reports to EPA that include only non-confidential generic chemical names and accession numbers. *See* JA048-50 (Comments of American Chemistry Council on EPA's Proposed Rule, Confidential Business Information Under the Toxic Substances Control Act, at 3-5, Docket ID No. EPA-HQ-OPPT-2021-0419-0044 (July 11, 2022) (hereinafter, "ACC Comments"));¹³ JA065-66 (Comments of American Fuel & Petrochemical Manufacturers on EPA's Proposed Rule, Confidential Business Information Under the Toxic Substances

¹³ Available at <https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0419-0044>.

Control Act, at 3-4, Docket ID No. EPA-HQ-OPPT-2021-0419-0052 (July 11, 2022) (hereinafter, “AFPM Comments”).¹⁴

Petitioners emphasized that reporting entities that lack knowledge of specific chemical identities cannot possibly assert or substantiate CBI claims for such identities. *See* JA049 (ACC Comments at 4); JA065-66 (AFPM Comments at 3-4). Nor do such entities reveal any confidential information merely by reporting a generic name and accession number. *See* JA049 (ACC Comments at 4). Moreover, ACC and its member company 3M Corporation¹⁵ both explained that it is common practice for a supplier of a chemical substance on the confidential portion of the Inventory to provide its downstream customers the accession number for the substance without revealing the underlying chemical identity. *See* JA197 (3M Comments at 4); JA050 (ACC Comments at 5). For these reasons, Petitioners asserted that EPA’s interpretation is inconsistent with TSCA. *See* JA049 (ACC Comments at 4); JA197 (3M Comments at 4). Accordingly, Petitioners requested that EPA clarify that CBI protection for a confidential chemical identity can only be

¹⁴ Available at <https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0419-0052>.

¹⁵ *See* American Chemistry Council, *ACC’s Manufacturer Members* <https://www.americanchemistry.com/about-acc/membership/manufacturermembers>. 3M’s comments on the proposed rule are available at <https://www.regulations.gov/comment/EPA-HQ-OPPT-2021-0419-0046>.

withdrawn by a company with knowledge of the specific and actual chemical identity. JA050 (ACC Comments at 5).

On June 7, 2023, EPA issued the Final Rule without incorporating the clarification requested by Petitioners. *See* JA001 (88 Fed. Reg. at 37,155). Rather, in the preamble to the final rule, EPA responded to Petitioners' concerns and 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." JA004 (88 Fed. Reg. at 37,158) (emphasis added). To support its assertion that the Final Rule is consistent with the agency's longstanding position, EPA cited three prior rulemaking documents in which EPA reiterated and implemented the requirement to assert and substantiate a confidentiality claim for chemical identity at the time of submission. *See id.* (quoting 74 Fed. Reg. 37,224, 37,224 (July 28, 2009); 76 Fed. Reg. 50,816, 50,825 (Aug. 16, 2011); and Response to Comments to the Proposed Rule, Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, at 17 (Feb. 4, 2020)¹⁶). Notably, none of the rulemaking documents cited by EPA address a scenario in which the reporting

¹⁶ Available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0320-0061>.

entity lacked knowledge of the confidential chemical identity and thus, submitted only non-confidential information to EPA such as a confidential substance's generic name and accession number.

Despite asserting that EPA's interpretation in the Final Rule is consistent with its longstanding position, EPA nonetheless "recognize[d]" that the concerns raised by Petitioners and other commenters "might arise in specific contexts." JA004 (88 Fed. Reg. at 37,158). EPA acknowledged, for example, that an entity lacking knowledge of the specific chemical identity could waive confidentiality for that chemical identity "when TSCA reporting rules implicate a universe of reporters from sectors that typically have little knowledge of the identities of specific chemical substances in their products," including "importers of articles[.]" *Id.* Rather than resolve those concerns, EPA asserted 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." *Id.* Such a future rule "*might* except all or a category of reporters from requirements to reassert chemical identity claims to maintain confidential Inventory status." *Id.* (emphasis added).

Under the Final Rule, a party asserting a CBI claim for a chemical identity must provide upfront substantiation by responding to the questions under 40 C.F.R. § 703.5(b)(3)-(4). These questions include whether the chemical identity appears in

any public documents, *id.* § 703.5(b)(3)(iii)(B), and whether a federal agency or a court has made a confidentiality determination regarding information associated with the chemical substance, *id.* § 703.5(b)(3)(v). If the submitter asserts that the chemical substance is not publicly known, it must certify that it has “searched the internet for the chemical substance identity,” including by chemical substance name, and did not find a reference to the chemical substance. *Id.* § 703.5(b)(4)(i). Clearly, this is an impossible task for a company that does not know the specific chemical identity of a substance and likely does not have a business interest in protecting the trade secret.

SUMMARY OF ARGUMENT

I. *EPA exceeded its authority under Section 14 of TSCA by issuing the Final Rule.* The text of TSCA and EPA’s interpretation of the statute confirm that specific chemical identities are routinely protected from disclosure as CBI. Where a manufacturer satisfies the requirements for asserting and substantiating a confidentiality claim for a specific chemical identity, TSCA prohibits EPA from disclosing that chemical identity except as provided in TSCA Section 14. *See* 15 U.S.C. § 2613(a). Nothing in Section 14 authorizes EPA to disclose the confidential chemical identity of a substance merely because that manufacturer’s downstream customer submitted information to EPA pursuant to TSCA that included only non-

confidential information about the substance such as a generic name or accession number.

II. *The Final Rule is arbitrary and capricious.* EPA failed to acknowledge or adequately explain its departure from its prior practice of recognizing that parties without knowledge of a chemical identity cannot assert and substantiate a CBI claim for such chemical identity. EPA claims that several prior rulemaking documents support its assertion that the Final Rule is consistent with EPA's longstanding position that CBI claims must be asserted and substantiated at the time of submission. However, the prior rulemaking documents that EPA relies on do not address a scenario in which the submitter lacks knowledge of the specific chemical identity. EPA also failed to articulate a rational justification for its current approach, and it failed to meaningfully address Petitioners' comments despite acknowledging that Petitioners raised valid concerns that could arise in future reporting contexts.

STANDING

Petitioners have associational standing to litigate on behalf of their members in this case. Many of Petitioners' members manufacture, process, and distribute chemicals subject to regulation under TSCA and as such, routinely submit information to EPA pursuant to TSCA. Therefore, Petitioners' members, such as ACC member 3M Corporation, are directly regulated and affected by the Final Rule, which affects the ability of manufacturers and processors of chemicals to

protect the confidentiality of information pertaining to their chemical substances by imposing new and revised procedures for asserting CBI claims under TSCA. *See State Nat. Bank of Big Spring v. Lew*, 795 F.3d 48, 53 (D.C. Cir. 2015) (“[T]here is ordinarily little question” that a regulated entity has standing to challenge an allegedly illegal rule under which it is regulated.) (quoting *Lujan v. Defs. of Wildlife*, 504 U.S. 555, 561-52 (1992)).

As Petitioners explained in their comments to the agency, the Final Rule threatens the property and financial interests that Petitioners’ members have in their CBI by restricting their ability to assert, substantiate, and maintain CBI claims. *See generally* JA046-62 (ACC Comments); JA063-67 (AFPM Comments); *see also Carpenter v. United States*, 484 U.S. 19, 26 (1987) (stating that CBI “has long been recognized as property” and finding Wall Street Journal “had a property right in keeping confidential and making exclusive use” of its CBI). The Final Rule therefore impacts Petitioners’ members’ operations and commercial interests, as the protection of CBI has substantial value for many companies and is a major factor in promoting innovation and research into new chemicals.

STANDARDS OF REVIEW

In determining whether an agency has acted within the bounds of its statutory authority, the “starting point for [this Court’s] interpretation of a statute is always its language.” *Lindeen v. SEC*, 825 F.3d 646, 653 (D.C. Cir. 2016) (internal quotation

marks and citation omitted). “[I]f the text alone is insufficient to end the inquiry, [the Court] may turn to other customary statutory interpretation tools, including structure, purpose, and legislative history.” *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 637 (D.C. Cir. 2021) (internal quotation marks and citations omitted).

Courts must set aside EPA action that is “in excess of statutory jurisdiction, authority, or limitations, or short of statutory right,” or that is “arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law.” 5 U.S.C. § 706(2). Arbitrary action includes “fail[ing] to consider an important aspect of the problem” and failing to articulate “a rational connection between the facts found and the choice made.” *Motor Vehicle Mfrs. Ass’n of United States, Inc. v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (internal quotation marks and citation omitted). The Court should “not defer to an agency’s conclusory or unsupported suppositions.” *Nat’l Shooting Sports Found., Inc. v. Jones*, 716 F.3d 200, 214 (D.C. Cir. 2013) (internal quotation marks and citation omitted). Furthermore, agency action is unlawful under the arbitrary and capricious standard if the agency “failed to consider an important aspect of the problem, [or] offered an explanation for its decision that runs counter to the evidence before the agency.” *State Farm*, 463 U.S. at 43.

Agency action is also arbitrary and capricious when an agency fails to respond meaningfully to significant comments. *See Del. Dep’t of Nat. Res. & Env’t Control v. EPA*, 785 F.3d 1, 16 (D.C. Cir. 2015) (explaining that “merely hearing

[commenters' concerns] is not good enough” and that “EPA must respond to serious objections”). An “unsupported and conclusory” response to comments does not fulfill the Agency’s obligation in this regard. *Chem. Mfrs. Ass’n v. EPA*, 28 F.3d 1259, 1266 (D.C. Cir. 1994).

ARGUMENT

I. EPA Exceeded Its Authority Under TSCA.

Section 14(a) of TSCA, which governs confidentiality claims, broadly commands that, except as otherwise provided in Section 14, EPA “shall not” disclose information that is exempt from disclosure under FOIA Exemption 4 (5 U.S.C. § 552) as a protected trade secret and CBI, and for which a confidentiality claim has been properly asserted and substantiated. 15 U.S.C. § 2613(a). EPA has acknowledged that “Congress was clear in section 14 [of TSCA] that confidentiality should be preserved to the maximum extent practicable without impairing the regulatory scheme of TSCA.” 42 Fed. Reg. 64,572, 64,591 (Dec. 23, 1977). Where a manufacturer satisfies the requirements for asserting and substantiating a confidentiality claim for chemical identity, nothing in Section 14 authorizes EPA to disclose chemical identity in the event a downstream customer reports on its activities involving the same chemical under TSCA using only non-confidential information.

A. Under TSCA, Specific Chemical Identities are Protectable from Disclosure as CBI.

Throughout TSCA's text, Congress made it clear that chemical identity can be protected from disclosure as CBI. For example, TSCA § 14(c)(1)(C) sets forth specific requirements for claiming chemical identity as confidential. 15 U.S.C. § 2613(c)(1)(C). Parties seeking to protect chemical identity from disclosure must “include a structurally descriptive generic name for the chemical substance” that meets certain requirements and that the EPA may disclose to the public. *Id.* Section 14(c)(4) instructs EPA to develop guidance for creating such generic names for confidential chemical identity reporting under TSCA. *Id.* § 2613(c)(4). Moreover, Section 14(g)(4) requires EPA to develop a system to assign unique identifiers to each specific chemical identity that is protected from disclosure as CBI. 15 U.S.C. § 2613(g)(4).

Section 8(b) requires EPA to maintain a confidential and non-confidential portion of the Inventory, and also establishes requirements for entities to maintain existing claims for “protection against disclosure of the specific chemical identity of the chemical substances as confidential pursuant to [Section 14].” 15 U.S.C. § 2607(b)(4)(B); *see also id.* § 2607(b)(5)(B)(ii) (establishing requirements for protecting chemical identity when persons intend to manufacture or process chemical substances that have been designated as inactive substances).

Consistent with the statute, EPA has long recognized that chemical identities warrant protection from disclosure as CBI. In the initial Inventory reporting rule, which EPA published in 1977 to assemble the original TSCA Inventory, EPA explained that in some instances “the fact that [a] chemical substance is manufactured or processed for commercial purposes in the United States is a confidential trade secret.” 42 Fed. Reg. at 64,591. Therefore, EPA found it necessary to establish procedures to allow any manufacturer or processor submitting information to EPA under TSCA to claim that a particular chemical identity should not be published in the Inventory. *See id.* Under these procedures, when EPA received a claim for confidentiality for the specific chemical identity of a substance, EPA would not publish the chemical identity in the Inventory and instead published a generic name for the chemical in an Appendix to the Inventory. *See id.* at 64,574. In subsequent updates to the Inventory, EPA assigned an accession number to each substance with a confidential identity and listed confidential substances in the public portion of the Inventory by their generic names and accession numbers. *See* 51 Fed. Reg. 21,438, 21,440 (June 12, 1986); *see also* 40 C.F.R. § 720.25(b)(1).

EPA also acknowledged that chemical identities are protectable CBI when it established procedures for assessing a Bona Fide Intent to Manufacture Notice under Section 5 of TSCA. *See* 42 Fed. Reg. at 64,591. Section 5 requires any person who intends to manufacture or import a “new chemical substance” to submit to EPA a

notice of such intent at least 90 days before initiating such activity. 15 U.S.C. § 2604(a)(1). To enable a person to determine whether the substance they intend to manufacture or import matches a chemical substance already listed in the confidential portion of the Inventory, or is a new chemical substance subject to notification under Section 5(a), EPA established procedures by which parties could request EPA to provide this information. Pursuant to 40 C.F.R. § 720.25, EPA will only disclose whether the chemical substance is on the confidential portion of the Inventory if EPA determines that the person has a bona fide intent to manufacture or import the chemical substance for a commercial purpose.

In crafting the procedures to demonstrate a bona fide intent, EPA explained that such approach would “protect trade secrets from disclosure to competitors” by allowing EPA to distinguish between a competitor’s “fishing expedition” and “a bona fide inquiry concerning the identities of confidential chemical substances on the inventory.” 42 Fed. Reg. at 64,591; *see also* 58 Fed. Reg. 7,661, 7,664 (Feb. 8, 1993) (updating Bona Fide Intent to Manufacture Notice requirements to “improve [EPA]’s ability to protect the CBI of the original submitters of Inventory-listed substances by enabling the EPA to be more selective about which Bona Fide Notice submitters are entitled to receive specific CBI concerning Inventory-listed substances”).

The harms resulting from public disclosure of a confidential chemical identity are clear and substantial. Such disclosure would result in significant competitive harm to the parties who have properly asserted and maintained confidentiality claims for the chemical identity. It would also harm parties that have not had to report or assert a CBI claim for the chemical identity but who nonetheless “may legitimately benefit from [its] confidential status[.]” *See* 82 Fed. Reg. 37,520, 37,527 (Aug. 11, 2017); *see also* p. 8 (Statement of the Case Part II), *supra*. The disclosure of such sensitive information would disrupt operations globally and interfere with contractual relationships. As EPA has acknowledged, a competitor in possession of a chemical identity known to be manufactured or processed for a commercial purpose could profit from such knowledge, including by using it to “narrow their research activities.” 42 Fed. Reg. at 64,590. Such harms would be compounded if the chemical substance “were newly synthesized and known only to the person reporting it to EPA[,], or if the substance were patentable[.]” *Id.* at 64,590.

B. EPA Exceeded Its Authority Under TSCA Section 14 By Authorizing Disclosure of Information Otherwise Entitled to Protection as CBI.

TSCA Section 14(a) plainly states that, except in limited circumstances, EPA “shall not disclose” trade secrets and commercial or financial information exempt from disclosure under FOIA Exemption 4, 5 U.S.C. § 552(a), so long as such information is reported to or otherwise obtained by EPA and meets the statutory

assertion and substantiation requirements in Section 14(c). 15 U.S.C. § 2613(a). Where a manufacturer satisfies the requirements for asserting and substantiating a claim for protecting chemical identity from disclosure, nothing in Section 14 authorizes EPA to disclose that confidential chemical identity merely because a downstream customer reports on its activities involving the chemical substance using a six-digit accession number, which EPA has consistently acknowledged is a *non-confidential identifier*. *E.g.*, 82 Fed. Reg. at 37,536 (accession number and generic name are “non-CBI identifiers”); 40 C.F.R. § 711.30(c) (“Generic chemical identities and accession numbers may not be claimed as confidential.”). In such instances, the underlying chemical identity remains a confidential trade secret that EPA “shall not disclose.” 15 U.S.C. § 2613(a).

The disclosure of confidential chemical identities based on the submission of a report containing only non-confidential identifiers does not fall within any of the limited exceptions to the broad statutory prohibition on disclosing CBI. *See* 15 U.S.C. § 2613(d). For instance, Congress authorized EPA to disclose confidential trade secrets if EPA finds it necessary to protect health or the environment against an unreasonable risk of injury. *See id.* § 2613(d)(3). Congress also authorized EPA to disclose confidential trade secrets to federal, state, local, and tribal governments in certain circumstances. *See id.* §§ 2613(d)(1)-(2), (d)(4)-(6). None of the exceptions in Section 14(d), however, authorize disclosure of confidential chemical

identities to the general public following the submission of TSCA reports that contain only non-confidential identifiers. And “[w]here Congress explicitly enumerates certain exceptions to a general prohibition, additional exceptions are not to be implied, in the absence of evidence of a contrary legislative intent.” *TRW Inc. v. Andrews*, 534 U.S. 19, 28 (2001) (quoting *Andrus v. Glover Constr. Co.*, 446 U.S. 608, 616-17 (1980)).

TSCA’s legislative history reinforces what the text makes clear: subject to narrow exceptions that do not apply in this case, Congress enacted a general “prohibition against disclosure of information exempt from mandatory disclosure under [FOIA] by reason of its” constituting a confidential trade secret. H.R. Rep. No. 94-1679, at 90, 94th Cong., 2d Sess. (Sept. 23, 1976) (Conf. Rep.). This baseline prohibition came from the House amendment, which “statutorily prohibit[ed] the disclosure of information which falls into [FOIA Exemption 4].” *Id.* at 89. Mindful of the need for EPA to have “full and complete access to information relevant to achieving the objectives of the bill,” the House amendment gave EPA “broad information gathering authority.” H.R. Rep. No. 94-1341, at 49-50, 94th Cong., 2d Sess. (July 14, 1976). At the same time, the House “recognize[d] that some information which [EPA] may obtain will be of tremendous competitive value to the person providing it” and thus, it included “specific prohibitions against release of such information so that the competitive position of those supplying the information

will be protected.” *Id.* at 50. Specifically, “any information which falls within the term ‘trade secrets and commercial or financial information obtained from a person and privileged or confidential’ is generally protected from disclosure by section 14.”

Id.

Put simply, the Final Rule is at odds with the general statutory prohibition on disclosure in TSCA Section 14. A downstream customer that submits a report to EPA referencing a chemical substance only by accession number does not reveal any confidential information or otherwise undermine a valid CBI claim for the substance’s underlying chemical identity. In those circumstances, because the specific chemical identity remains a confidential trade secret, EPA “shall not disclose” the identity unless one of the narrow exceptions in Section 14(d) applies. 15 U.S.C. §§ 2613(a), (d). EPA cannot rewrite the plain terms of the statute to carve out a new exception to the general prohibition on disclosure.

II. The Final Rule Arbitrarily and Capriciously Removes CBI Protections for Chemical Identities Based on the Reporting of Non-confidential Information by Entities Unable to Assert and Substantiate CBI Claims.

The Final Rule states that an entity lacking knowledge of a specific chemical identity can nonetheless waive confidentiality for that chemical identity by submitting a report to EPA that includes the chemical’s non-confidential identifier. JA004 (88 Fed. Reg. at 37,158). EPA’s interpretation is inconsistent with past agency practice. Given the agency’s failure to acknowledge this change and provide

a “reasoned explanation for the change,” *Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016), and its failure to “consider an important aspect of the problem” as demonstrated by its unsatisfactory responses to Petitioners’ comments, *State Farm*, 463 U.S. at 43, this aspect of the TSCA CBI is arbitrary and capricious.

A. EPA Failed to Acknowledge or Explain Its Departure from Its Prior Approach to Reporting Using Non-CBI Identifiers.

When an agency changes an existing policy, it must “display awareness that it is changing position” and “show that there are good reasons for the new policy.” *FCC v. Fox Television Stations, Inc.*, 556 U.S. 502, 515 (2009). The agency must provide a “reasoned explanation for the change,” including by “show[ing] that there are good reasons for the new policy.” *Encino Motorcars, LLC*, 579 U.S. at 221 (internal quotation marks and citation omitted). EPA has neither acknowledged that it is departing from prior agency policy, nor has it provided a reasonable explanation for its new approach.

EPA’s current approach is inconsistent with agency action dating back to the early implementation of TSCA. Historically, EPA recognized that a party lacking knowledge of chemical identity cannot assert a confidentiality claim for that identity, nor could they substantiate such a claim. For example, in the initial 1977 inventory rule, EPA proposed a joint reporting mechanism to allow companies without knowledge of specific chemical identity information to fulfill their reporting obligations without requiring the underlying manufacturer of the substance to waive

CBI protection for confidential chemical identity. In complying with the reporting requirements under TSCA Section 8, an importer lacking knowledge of a specific chemical identity could “arrange that he would send directly to EPA the trade name of the imported chemical substance . . . and that a foreign manufacturer . . . would submit the specific chemical identity of the trade name substance.” 42 Fed. Reg. at 64,582. EPA expected that this joint reporting mechanism would be useful to address scenarios in which information required to be reported is a confidential trade secret. *Id.*

To provide another example, consider the Inventory Reset Rule, which required every manufacturer and importer to notify EPA of each chemical substance it manufactured for a nonexempt commercial purpose during the prescribed look-back period. 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[.]” 82 Fed. Reg. at 37,536. These two options are: either engage in joint reporting or report by selecting information from a pick list containing non-CBI identifiers, including EPA accession number and generic name.

Under the joint reporting procedures, the submitter was required to provide any information on the specific chemical identity “that it has in its possession,” and the supplier separately provided information on the specific chemical identity directly to EPA “in a manner that protects the supplier’s CBI from the submitter[.]”

Id. Alternatively, if the submitter has in its possession only the EPA-assigned accession number and generic name, it may satisfy its reporting obligations by selecting the relevant chemical substance from a pick list. *Id.* Under that rule, the pick list did not contain CBI and instead listed confidential substances by EPA accession numbers and generic names, as they appeared on the publicly available non-confidential Inventory. *Id.* Notably, EPA explained that submitters who use the pick list do not need to supply CBI to EPA “[b]ecause the chemical identity information selected from the pick list and transmitted on the [Notice of Activity] form will not be CBI[.]” *Id.*

In subsequent guidance regarding reporting under the Inventory Reset Rule, EPA encouraged parties to “share non-CBI identifiers, such as EPA accession numbers and generic names, with their customers for confidential substances” to avoid the need for a joint submission.¹⁷ Such guidance demonstrates EPA’s understanding that parties in possession of only a chemical substance’s accession number and generic name lack knowledge of the underlying specific chemical

¹⁷ *TSCA Inventory Notice of Activity Form B Questions and Answers* at 2, available at https://www.epa.gov/sites/default/files/2019-07/documents/tsca_inventory_notification_active-inactive_rule_questions_and_answers_on_noa_form_b_.pdf (last visited Nov. 6, 2023).

identity, and therefore are not in any position to assert and substantiate a CBI claim for the chemical identity.

In the Final Rule, EPA does not acknowledge, let alone justify, why it departed from its prior approach to safeguarding CBI claims for chemical identity in scenarios where downstream customers who lack knowledge of specific chemical identity must report information under TSCA. EPA fails to acknowledge, as it has in the past, that parties lacking knowledge of chemical identity cannot assert and substantiate a confidentiality claim for the chemical identity. Due to this failure, EPA also departs from its past practice of providing safeguards to protect against the disclosure of CBI in such instances, such as by shifting the obligation to assert and substantiate a CBI claim for the chemical identity to the supplier. Rather, under 40 C.F.R. § 703.5 of the Final Rule, the failure to assert and substantiate a CBI claim for chemical identity, *even though the reporter lacks knowledge of chemical identity*, results in a waiver as to all parties, including manufacturers who previously received CBI protection for that chemical identity.

By failing to provide a “reasoned analysis” indicating that EPA is departing from its prior practice and instead “casually ignor[ing]” such precedent, EPA acted arbitrarily and capriciously. *Ramaprakash v. FAA*, 346 F.3d 1121, 1124-25 (D.C. Cir. 2003) (internal quotation marks and citation omitted).

B. EPA's Explanation of the Final Rule Runs Counter to the Record.

EPA for its part cites to several prior rulemaking documents to assert that it has long maintained the position that a party that fails to assert and substantiate a confidentiality claim for a chemical identity at the time of submission waives CBI protection as to the chemical identity. JA004 (88 Fed. Reg. at 37,158). However, neither EPA's explanation nor the prior documents that it cites address the specific scenario at issue here where the reporting entity lacks the information needed to assert or substantiate a CBI claim for a chemical identity and reports only non-confidential information. *See Mich. Wis. Pipe Line Co. v. Fed. Power Comm'n*, 520 F.2d 84, 89 (D.C. Cir. 1975) (agency's reliance on precedent "without recognition of the substantial differences" is not reasoned decision-making). EPA thus failed to "articulate a satisfactory explanation for its action." *State Farm*, 463 U.S. at 43.

First, EPA cites the 2009 update to the TSCA Inventory, in which certain manufacturers failed to assert a claim of confidentiality for the chemical identity for which they were reporting and as a result, 530 chemicals were moved from the confidential to the public portion of the Inventory. JA004 (88 Fed. Reg. at 37,158 (citing 74 Fed. Reg. 37,224, 37,224 (July 28, 2009))). Next, EPA cites the 2011 TSCA Inventory Update Rule, which merely reiterates that "failure to identify [a] chemical identity as CBI and complete upfront substantiation will waive any CBI

claim to the chemical identity[.]” JA004 (*id.*, (citing 76 Fed. Reg. 50,816, 50,825 (Aug. 16, 2011))).

Finally, EPA cites its Response to Comments for the 2020 Procedures for Review of Confidential Business Information Claims for the Identity of Chemicals on the TSCA Inventory wherein EPA responded to commenters’ concerns “*that a decision by one company to abandon CBI protection of a specific chemical identity would eliminate the ability of any other company to claim the specific chemical identity as CBI*”¹⁸ by stating: “[i]f 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[.]” JA004 (88 Fed. Reg. at 37,158 (citing U.S. EPA, Response to Comments on the Proposed Rule, Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, at 17 (Feb. 4, 2020))).

None of the prior rulemaking documents upon which EPA relies envisions a scenario in which EPA removes CBI protection for a specific chemical identity solely based on reporting using an accession number or other non-confidential

¹⁸ U.S. EPA, Response to Comments on the Proposed Rule, Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory, at 16 (Feb. 4, 2020), available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0320-0061>.

identifier. Indeed, each of the prior statements that EPA relies on appears to assume that the entity waiving the CBI claim actually had knowledge of the specific chemical identity. In those instances, failure to claim the specific chemical identity as CBI and to complete upfront substantiation for that claim *should* eliminate the ability to protect the chemical identity from disclosure. But if the reporting entity lacks knowledge of the specific chemical identity and therefore is unable to assert or substantiate a CBI claim for that identity, it defies logic that the submission of non-confidential identifiers for a confidential substance could result in a waiver of a properly substantiated CBI claim for that substance's specific identity.

EPA's reference to factually distinct scenarios in an attempt to "invok[e] a sort of 'consistency' rationale" without acknowledgement or discussion of the differences fails to withstand scrutiny. *Cal. Pub. Utils. Comm'n v. FERC*, 20 F.4th 795, 802 (D.C. Cir. 2021) (citation omitted). Accordingly, this Court should not defer to EPA's "conclusory [and] unsupported suppositions." *Jones*, 716 F.3d at 214 (internal quotation marks and citation omitted).

C. EPA Failed to Consider and Respond Adequately to Comments.

EPA's approach under the Final Rule is arbitrary and capricious because EPA failed to respond meaningfully to significant comments. "[A]n agency must 'demonstrate the rationality of its decision-making process by responding to those comments that are relevant and significant.'" *Cement Kiln Recycling Coal. v. EPA*,

493 F.3d 207, 225 (D.C. Cir. 2007) (quoting *Grand Canyon Air Tour Coal. v. FAA*, 154 F.3d 455, 468 (D.C. Cir. 1998)). Such failure generally demonstrates that EPA’s decision “was not based on a consideration of the relevant factors.” *Lilliputian Sys., Inc. v. Pipeline & Hazardous Materials Safety Admin.*, 741 F.3d 1309, 1312 (D.C. Cir. 2014) (internal quotation marks and citation omitted).

During the rulemaking process, Petitioners raised concerns about EPA’s view that an entity who lacks knowledge of a specific chemical identity—and thus, is not in a position to assert and substantiate a CBI claim for such information—could eviscerate an otherwise properly substantiated CBI claim by virtue of submitting a report containing a non-confidential identifier such as an accession number. *See* JA049 (ACC Comments at 4) (explaining that there is no legal basis under TSCA Section 14 for EPA to withdraw or deny CBI protection for a particular chemical identity when a company reports only a substance’s generic name and accession number because that company “has not revealed any confidential chemical identity information”); JA197 (3M Comments at 4) (EPA’s final rule is grossly unfair because it requires a downstream reporter to either “provide information to EPA that it does not have in its possession” or waive CBI protection for the specific chemical identity as to all other entities); JA065-66 (AFPM Comments at 3-4) (entities lacking knowledge of chemical identity are not able to assert or substantiate a confidentiality claim for that chemical identity).

EPA “recognize[d]” and “appreciate[d]” commenters’ concerns that companies lacking knowledge of specific chemical identity could waive a CBI claim previously asserted by another company under this rule. *See* JA004 (88 Fed. Reg. at 37,158); JA231 (Response to Comments at 18). Rather than respond meaningfully to these concerns, however, EPA offered two unsatisfactory responses.

First, EPA stated that “the best way to address [these] concerns” is in the context of subsequent, specific TSCA reporting rules, rather than in the Final Rule, which addresses a broad variety of reporting contexts where this problem may not arise. *See* JA004 (88 Fed. Reg. at 37,158); JA231 (Response to Comments at 18). However, “EPA cannot get away so easily from its obligations . . . to respond to relevant and significant comments.” *Del. Dep’t of Nat. Res. & Env’t Control*, 785 F.3d at 15 (internal quotation marks and citation omitted).

By suggesting that it might address Petitioners’ concerns in future rulemaking, EPA effectively concedes that its approach in the Final Rule could result in an arbitrary outcome whereby an entity without knowledge of a specific confidential chemical identity could waive another company’s properly asserted and substantiated CBI claim. The possibility that EPA could take measures to address Petitioners’ concerns in a future rulemaking does not save this rule from being arbitrary. *Ramaprakash*, 346 F.3d at 1130 (rejecting as arbitrary and capricious agency proposal to address its flawed actions at a later time to account for “specific

facts of future cases”); *Am. Tel. & Tel. Co. v. FCC*, 978 F.2d 727, 733 (D.C. Cir. 1992) (holding that it was arbitrary and capricious for agency to dismiss a stakeholder’s complaint “with only a promise to address the legal issue it raised in a future rulemaking”). Moreover, EPA’s rationale is irrational; in those contexts where the problem of downstream CBI waiver does not arise, there is no harm to an overinclusive rule universally preventing downstream CBI waiver. By contrast, there is manifest harm from the failure to prevent downstream CBI waiver.

EPA’s offer to kick the can down the road is insufficient to protect chemical identities as CBI *now*. EPA has made it clear that if a submitting entity fails to assert and substantiate a confidentiality claim at the time of submission, the chemical identity will be moved to the public portion of the Inventory without further notice. *See* 40 C.F.R. § 703.5. Once a chemical identity is moved to the public portion of the Inventory, “[n]o person may assert a new claim” to protect the specific chemical identity from disclosure, either under Section 8 or 14. 15 U.S.C. § 2607(b)(8). In other words, by the time EPA has finalized specific TSCA reporting rules to account for a reporting entity’s lack of knowledge, CBI chemical identities may already have been disclosed to the public and cannot be moved back to the confidential portion of the Inventory. *Cf. Ruckelshaus v. Monsanto Co.*, 463 U.S. 1315, 1317 (1983) (trade secrets disclosed to the public cannot “be made secret again”).

Second, EPA “disagree[d] with [Petitioners’] comments in part” by explaining that confidential inventory protection was a tool devised by EPA soon after TSCA’s enactment to balance competing interests between Sections 8 and 14, and that EPA has long maintained that chemicals reported without a CBI claim and any required supporting information were subject to removal from the confidential to the public portion of the Inventory and that manufacturers must diligently maintain CBI claims. JA231 (Response to Comments at 18). But this nonresponsive explanation reflects EPA’s failure to “engage [with] the arguments raised before it.” *NorAm Gas Transmission Co. v. FERC*, 148 F.3d 1158, 1165 (D.C. Cir. 1998) (quoting *K N Energy, Inc. v. FERC*, 968 F.2d 1295, 1303 (D.C. Cir. 1992)).

There is no dispute that entities with actual knowledge of specific chemical identity must assert and substantiate CBI claims should they wish to protect that identity as CBI. By contrast, when a reporting entity lacks knowledge of the specific chemical identity that is protected as CBI—and therefore lacks the information needed to assert and substantiate a CBI claim—the submission of a report containing only non-confidential information has no bearing on how diligently the original claimant is maintaining its CBI claims. Such non-confidential submissions should not waive CBI protections for the underlying specific chemical identity.

As Petitioners explained in their comments, it is not customary for suppliers to provide their downstream customers with confidential chemical identities. JA050

(ACC Comments at 5); JA197 (3M Comments at 4). Instead, suppliers may provide non-confidential identifiers such as the accession number and generic name to inform their customers of the chemical substance's Inventory status. JA197 (3M Comments at 4). EPA's failure to respond to Petitioners' comments challenging a "fundamental premise" underlying the Final Rule—that any party with an accession number or other non-confidential identifier also possesses the information needed to assert and substantiate a confidentiality claim for that confidential chemical substance—is arbitrary and capricious. *Carlson v. Postal Regul. Comm'n*, 938 F.3d 337, 344 (D.C. Cir. 2019) (internal quotation marks and citation omitted).

CONCLUSION

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

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Respectfully submitted,

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CERTIFICATE OF COMPLIANCE

This brief complies with the type-volume limitation of Federal Rule of Appellate Procedure 32(a)(7)(B) and this Court's briefing order because this brief contains 8,625 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and Circuit Rule 32(e)(1).

This brief complies with the typeface requirements of Federal Rule of Appellate Procedure 32(a)(5) and the type-style requirements of Federal Rule of Appellate Procedure 32(a)(6) because this brief has been prepared in a proportionally spaced typeface using Microsoft Office Word in 14-point Times New Roman font.

Dated: April 11, 2024

/s/ David Y. Chung
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CERTIFICATE OF SERVICE

I hereby certify that on April 11, 2024, I have caused the foregoing to be filed electronically 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. I certify that all participants in the case are registered CM/ECF users and that service will be accomplished by the appellate CM/ECF system.

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