ORAL ARGUMENT NOT YET SCHEDULED

No. 23-1166 (*consolidated with No. 23-1204*)

UNITED STATES COURT OF APPEALS
FOR THE DISTRICT OF COLUMBIA CIRCUIT

ENVIRONMENTAL DEFENSE FUND,

Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY, ET AL.,

Respondents.

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

INITIAL OPENING BRIEF OF PETITIONER ENVIRONMENTAL DEFENSE FUND

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November 8, 2023

CERTIFICATE AS TO PARTIES, RULINGS, AND RELATED CASES

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

A. Parties

The parties in this matter include:

Petitioners

1. Environmental Defense Fund (Case No. 23-1166)
2. American Chemistry Council and American Fuel & Petrochemical Manufacturers (Case No. 23-1204)

On August 9, 2023, the Court ordered consolidation of the two cases.

Respondents

United States Environmental Protection Agency and Michael Regan, Administrator of the United States Environmental Protection Agency

Intervenors

On September 19, 2023, the Court granted leave to Environmental Defense Fund to intervene in support of respondents in Case No. 23-1204 and granted leave to American Chemistry Council to intervene in support of respondents in Case No. 23-1166.

Amici Curiae:

None at present

B. Ruling Under Review

These consolidated cases involve a final agency action of the United States Environmental Protection Agency, titled "Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)," which appears in the Federal Register at 88 Fed. Reg. 37,155 (June 7, 2023).

C. Related Cases

These consolidated cases have not previously been before this Court or any other court, and the undersigned is not aware of any related cases as defined by D.C. Circuit Rule 28(a)(1)(C).

/s/ Samantha Liskow
Samantha Liskow

RULE 26.1 DISCLOSURE STATEMENT

Environmental Defense Fund, organized and existing under the laws of the State of New York, is a national nonprofit organization that links science, economics, and the law to create solutions to urgent environmental problems.

Pursuant to D.C. Circuit Rule 26.1, Environmental Defense Fund certifies that it is a nonprofit corporation that does not issue stock, has no parent companies, and in which no publicly held corporations have any form of ownership interest.

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GLOSSARY OF ABBREVIATIONS

Pursuant to Circuit Rule 28(a)(3), the following is a glossary of abbreviations used in this brief:

ADD	Addendum
CBI	Confidential Business Information
EDF	Environmental Defense Fund
EPA	Respondents United States Environmental Protection Agency and Administrator Michael Regan
FOIA	Freedom of Information Act
JA	Joint Appendix
Rule	United States Environmental Protection Agency, "Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)," 88 Fed. Reg. 37,155 (June 7, 2023)
TSCA	Toxic Substances Control Act

STATEMENT OF JURISDICTION

This Court has jurisdiction under Section 19 of the Toxic Substances Control Act ("TSCA"), 15 U.S.C. § 2618(a)(1)(A), to review the final rule of Respondents U.S. Environmental Protection Agency, *et al.* (hereinafter, collectively "EPA" or "Agency"), 88 Fed. Reg. 37,155 (June 7, 2023) ("Rule"), Joint Appendix ("JA") __, and Environmental Defense Fund ("EDF") timely filed its petition.

STATUTES AND REGULATIONS

Pertinent statutes and regulations appear in this brief's addendum.

ISSUES PRESENTED

1. Whether EPA's Rule adopting a regulatory definition of "health and safety study" inconsistent with TSCA's definition, which will deny the public access to information about chemicals to which they may be exposed, is contrary to TSCA or arbitrary and capricious.

2. Whether EPA's Rule exempting confidentiality claims for information specifying a chemical's identity from substantiation and review, whenever the claim was asserted before the chemical's commercialization, is contrary to TSCA or arbitrary and capricious.

3. Whether EPA's Rule giving the Agency discretion to depart from its obligations under TSCA to deny confidentiality claims that do not meet statutory requirements and to release information to the public where those requirements are not met is contrary to TSCA or arbitrary and capricious.

STATEMENT OF THE CASE

I. Legal Framework

Congress enacted TSCA in 1976 to regulate chemicals in commerce comprehensively—from their initial manufacture to ultimate disposal—to "prevent unreasonable risks of injury to health or the environment." S. Rep. No. 94-698, at 1 (1976); Pub. L. No. 94-469, 90 Stat. 2003 (codified at 15 U.S.C. § 2601 *et seq*.) (1976). EPA does so under numerous provisions, including mandates that it review and approve any new chemical before it enters the U.S. market, 15 U.S.C. § 2604, and that it review and regulate those chemicals that are already on the market and pose the highest risk to public health. 15 U.S.C. § 2605; *see generally* Kevin McLean, *Three Years After – Where Does Implementation of the Lautenberg Act Stand?*, Harvard Law School Environmental & Energy Law Program (2020), https://eelp.law.harvard.edu/wp-content/uploads/McLean-TSCA.pdf.

As EPA has stated, access to chemical information by those outside EPA is consistent with TSCA's purposes and is important for numerous reasons, including informing consumers, workers, and communities about chemicals to which they may be exposed and empowering these parties, as well as state, local, and Tribal governments, businesses, and researchers, to understand and meaningfully participate in EPA decisionmaking on chemicals. EPA Office of Pollution Prevention and Toxics, *Final Action Plan: TSCA Confidential Business*

Information Reform, 000001-8 (June 1994), https://www.regulations.gov/document/EPA-HQ-OPPT-2002-0054-0075.

TSCA's provisions require EPA to share certain information with the public. For example, TSCA authorizes EPA to require companies to develop information about chemicals and expressly mandates that EPA make that information public. 15 U.S.C. §§ 2603(d), 2604(b)(3). Similarly, EPA must disclose the bases for its scientific and regulatory decisions on chemicals it reviews. *See* 15 U.S.C. § 2625(j). These disclosure mandates are all "subject to [Section 14]," 15 U.S.C. § 2613, in which Congress described what information EPA could lawfully protect from disclosure and what it could not. 15 U.S.C. §§ 2603(d), 2604(b)(3), 2625(j).

In TSCA Section 14, Congress expressly required EPA to disclose certain information and withhold, under specific conditions, other information EPA finds to be confidential business information ("CBI"). 15 U.S.C. § 2613. In that Section and elsewhere in TSCA, Congress elevated the importance of broad access to certain categories of chemical information, with a particular focus on health and safety studies and associated information. It classified that category broadly as "information not protected from disclosure," even where companies might have proprietary interests in blocking disclosure, subject to two narrow exceptions (where disclosure would reveal a chemical's manufacturing process or mixture proportions). 15 U.S.C. § 2613(b)(2).

Over the decades after TSCA's initial passage, however, it became clear that the transparency Congress sought was not achieved. EPA's policy and practice were skewed toward denying public access indefinitely to the information companies claimed as confidential, with few requirements for the companies to justify those claims and with no EPA review of the vast majority of those claims. Richard Denison, *Ten Essential Elements in TSCA Reform*, 39 Envtl. L. Rep. 10020 (2009). Periodically, EPA documented shortcomings plaguing its system governing disclosure, such as in its 1994 reform action plan. *See* EPA Office of Pollution Prevention and Toxics, *Final Action Plan: TSCA Confidential Business Information Reform*, https://www.regulations.gov/document/EPA-HQ-OPPT-2002-0054-0075. Little changed, however. As one measure, a report by the Government Accountability Office issued a decade after EPA's reform action plan quoted an EPA official reporting that the Agency challenged only about 14 CBI claims per year. GAO-05-458, *Chemical Regulation—Options Exist to Improve EPA's Ability to Assess Health Risks and Manage its Chemical Review Program*, 33 (2005).

A. TSCA Reform and Increased Transparency

In 2016, Congress passed the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("Lautenberg Act"), substantially amending TSCA. Pub. L. No. 114-182, 130 Stat. 448 (2016) (codified at 15 U.S.C. § 2601 *et seq.*). As EPA

states, the Act "included several significant changes to TSCA section 14." Rule at 37,156 [JA__]. Confidentiality claims must now be asserted, and most must be substantiated by the claimant and reviewed by EPA, in accordance with new requirements established by the Lautenberg Act. *Id.* Congress expanded public access to information that it designated as not protected from disclosure or that EPA finds does not meet TSCA confidentiality requirements. *Id.* Congress also expanded access to CBI by state, local, and Tribal governments, as well as to health, environmental and medical professionals. 15 U.S.C. § 2613(d).

As a result of these revisions, TSCA significantly limits the extent to which companies can assert and EPA can withhold information as confidential. Under subsection 2613(a), EPA may not withhold information unless the company claiming confidentiality establishes that: (1) the information meets the requirements for a trade secret or privileged and confidential information under the Freedom of Information Act, 5 U.S.C. § 552(b)(4); and (2) the information meets the TSCA-specific requirements for confidentiality established in 15 U.S.C. § 2613(c). 15 U.S.C. § 2613(a).

Three sets of TSCA provisions are particularly relevant to the claims raised in this lawsuit regarding: (1) health and safety studies; (2) the specific chemical identity of new chemicals; and (3) EPA's obligations to deny improper confidentiality claims and disclose non-protected information.

B. Health and Safety Studies

In the Lautenberg Act, Congress reiterated and expanded provisions ensuring public access to information related to the use and safety of chemical substances by providing that "any health and safety study" along with "any information…from a health and safety study" *per se* cannot be made confidential. 15 U.S.C. §§ 2613(b)(2)(A)(ii), 2613(b)(2)(B). The only such information that may not be disclosed is specific "information…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." *Id.* at § 2613(b)(2). However, Congress did not protect "general descriptions" of such processes. *Id.* at § 2613(b)(3)(B).

C. Specific Chemical Identity of New Chemicals

A company must apply for EPA approval before it can begin manufacturing a "new chemical"—one that has not been made in or imported into the United States. 15 U.S.C. § 2604. EPA must review the application, which includes information about how the chemical will be made, used, distributed and disposed of, and available studies about its health and environmental effects and exposures, to determine the potential risk posed by the new chemical. 15 U.S.C. § 2604(d)(1). If EPA finds the chemical may present unreasonable risk, the Agency must

regulate the chemical, up to and including blocking market access, as necessary to protect human health and the environment. *Id*. at §§ 2604(e), 2604(f).

TSCA requires that EPA operate this new chemical review process transparently. The Agency must quickly inform the public when it receives a new chemical application, and it must disclose all non-confidential information contained in the application, including information about the exposures and health effects of the new chemical, to interested people. 15 U.S.C. §§ 2604(d)(1), 2604(d)(2), 2604(h)(6), 2613.

When a company submits its new chemical application, it must give EPA the specific chemical identity ("chemical identity"), which is information that specifies the structure and composition of the chemical substance. The company may claim the chemical identity as confidential in all documents that are part of the application. 15 U.S.C. § 2613(c)(2)(G). For the period preceding any commercial distribution of the chemical, the company is not required to substantiate those confidentiality claims and EPA is not required to review them. *Id*; 15 U.S.C. § 2613(g)(1)(A).

If EPA, after reviewing the application, gives a company approval to manufacture a new chemical, the company must submit a Notice of Commencement ("manufacture notice") within 30 days of starting manufacture. 40 C.F.R. § 720.102. If the company makes a confidentiality claim for the chemical's

identity in the manufacture notice, it must substantiate the claim and the claim is subject to EPA review. 15 U.S.C. § 2613(g)(1)(A). Manufacture notices, however, do not contain information about the health and environmental effects of the chemical. 40 C.F.R. § 720.102(c).

At this stage, companies must now substantiate their claims for confidentiality of chemical identities in their new chemical application documents, as TSCA expressly provides that the exemption from substantiation applies only "prior to the date on which a chemical substance is first offered for commercial distribution." 15 U.S.C. § 2613(c)(2)(G). Also, these earlier claims must now be reviewed by EPA. *Id.* at § 2613(g)(1)(A). This greater focus on the claims coincides with the commercial production of the new chemical, a point when concerns about the impacts of the chemicals would be heightened.

D. Mandatory confidentiality claim review and information disclosure

TSCA mandates a three-step procedure for establishing that information is entitled to confidential treatment by EPA. First, a company must assert the claim and include a certified statement supporting it. 15 U.S.C. §§ 2613(c)(1)(A), 2613(c)(5). The company must state that it has:

> (i) taken reasonable measures to protect the confidentiality of the information;
>
> (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

> (iii) a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the [company]; 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).

The second procedural step is substantiation. Except for those claims exempted by TSCA section 14(c)(2), "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim." 15 U.S.C. § 2613(c)(3). EPA has recognized that substantiation must occur at the time information is submitted to be considered for confidential protection. EPA, *Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims Under the Toxic Substances Control Act (TSCA)*, 82 Fed. Reg. 6522, 6522 (Jan. 19, 2017).

At the third procedural step, EPA must review certain claims and determine whether to approve or deny each claim. 15 U.S.C. § 2613(g). EPA must review "all" confidentiality claims for specific chemical identities (except for claims in new chemical applications for chemicals that are not commercialized). 15 U.S.C. § 2613(g)(1)(C)(i). EPA must also review a representative subset of all other confidentiality claims. *Id.* at § 2613(g)(1)(C)(ii).

If EPA denies a claim, the Agency must, in most cases, notify the claimant, who may then file a lawsuit against EPA challenging disclosure. *Id.* at

§ 2613(g)(2)(A), (D). EPA must make its confidentiality determinations available to the public. *Id.* at § 2625(j)(1).

II. The Challenged Rule

EPA published the proposed rule in May 2022. 87 Fed. Reg. 29,078 (May 12, 2022) [JA __]. EDF and others submitted comments. *See* EDF, CBI Rule Comments, EPA-HQ-OPPT-2021-0419-0050 [JA__] ("EDF Comments"); Earthjustice et al., CBI Rule Comments, EPA-HQ-OPPT-2021-0419-0049 [JA__] ("Earthjustice Comments"). In its extensive comments, EDF described various problems with the proposal, including those that are the subject of this petition. EDF Comments at 15-18, 23-26, 30-35, 45, 68 [JA__-__]. EPA published its Rule on June 7, 2023. 88 Fed. Reg. 37,155 [JA__] ("Rule"). In the Rule, EPA retained many of the provisions, as proposed, that EDF had urged the Agency to modify or eliminate. The specific regulatory provisions EDF challenges are discussed in the argument below.

SUMMARY OF THE ARGUMENT

EPA repeatedly violated TSCA's statutory text in its 2023 Rule and erred in favor of withholding instead of disclosing information. The Rule will deprive the public of information relevant to understanding the health and environmental impact of chemicals—information to which the public is entitled under TSCA.

EDF challenges three aspects of the Rule.

First, EPA's rewrite of TSCA to narrow its expansive definition of "health and safety study" undermines Congress' mandate that "any information" from a health and safety study, including underlying information, is "information not protected from disclosure," subject to two narrow exceptions. EPA also failed to respond meaningfully to commenters' concerns about the definitional carveouts.

Second, the Rule will block public access to chemicals' identities when companies claim them confidential in the health and safety documents they submit with their applications to make or import a new chemical in the United States. TSCA requires a company to substantiate—and EPA to review—confidentiality claims for a chemical identity in those documents once the chemical enters the market. However, EPA's Rule would exempt those claims from substantiation, and review by EPA. EPA's granting of indefinite confidentiality of this information also constitutes a reversal of long-standing regulations that the Agency did not adequately explain.

Third, the Rule contains unlawful discretionary provisions that will result in the denial of public access to information. The Rule states that EPA only "may" deny confidentiality claims when a company fails to meet the requirements for making a valid claim and that EPA only "may" release information to the public when it cannot validly be withheld under TSCA. In doing so, and without adequate explanation, EPA replaced regulations that properly implemented Congress' disclosure mandates.

STANDARD OF REVIEW

TSCA incorporates the Administrative Procedure Act standards of review. 15 U.S.C. § 2618(c)(1)(B). Thus, under TSCA, this Court holds unlawful and sets aside agency action that is "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right." 5 U.S.C. § 706(2)(C); 15 U.S.C. § 2618(c)(1)(B). The Court also sets aside agency action that is "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A); 15 U.S.C. § 2618(c)(1)(B). "It is well established that when the statute's language is plain, the sole function of the courts … is to enforce it according to its terms." *Lamie v. U.S. Trustee*, 540 U.S. 526, 534 (2004) (internal quotation marks and citations omitted). An agency action that violates a statute is "not in accordance with law within the meaning of 5 U.S.C. § 706(2)(A)." *NRDC*

v. Regan, 67 F.4th 397, 411 (D.C. Cir. 2023) (Pan, J., concurring) (citations omitted).

Agency action is arbitrary and capricious if the agency "relies upon improper factors, ignores important arguments or evidence, [or] fails to articulate a reasoned basis" for its action. *NRDC v. EPA*, 822 F.2d 104, 111 (D.C. Cir. 1987). Moreover, when an Agency's "explanation for a contested action is lacking or inadequate, it will not survive judicial review." *EDF v. FERC*, 2 F.4th 953, 968 (D.C. Cir. 2021); *see also Encino Motorcars, LLC v. Navarro*, 579 U.S. 211, 221 (2016). "[T]he overarching question" is whether the Agency's "decisionmaking was reasoned, principled, and based upon the record." *EDF v. FERC*, 2 F.4th at 967-68 (internal quotation marks omitted).

STANDING

EPA's Rule will result in the denial of access to information about chemicals in the United States to which EDF, and the broader public, is entitled under TSCA. *See* Declaration of Maria Doa ("Doa Decl.") ¶¶21-29, Addendum ("ADD") at 10-16. EDF has used similar information to achieve its purpose and goals, including environmental research and public education, and plans to continue doing so. *Id.* at ¶¶3-20, ADD2-9. A decision by the Court in EDF's favor would remedy the harm done to EDF by invalidating the regulatory provisions that unlawfully prevent the disclosure of such information. *Id.* at ¶¶28-29, ADD14-15; *Ascendium Educ. Sols.,*

Inc. v. Cardona, 78 F.4th 470, 478 (D.C. Cir. 2023) (holding that vacatur of a challenged rule satisfies the redressability requirement for standing). For these reasons, along with the reasons described in this brief and in the accompanying declaration, EDF has "a quintessential claim of informational standing." *EDF v. EPA*, 922 F.3d 446, 452 (D.C. Cir. 2019); *see generally* Doa Decl., ADD2-16.

ARGUMENT

I. EPA has unlawfully narrowed TSCA's definition of "health and safety study"

In TSCA, Congress defined "health and safety study" broadly:

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

15 U.S.C. § 2602(8).

In its Rule, EPA has narrowed Congress' expansive definition by simply declaring multiple categories of information from a health and safety study "not part of a health and safety study," thereby shielding that information from public disclosure. 40 C.F.R § 703.3.

A. By redefining health and safety study, EPA has impermissibly rewritten TSCA

EPA's carveouts undermine Congress' instruction that "*any* information" from a health and safety study is not to be protected from disclosure. 15 U.S.C. § 2613(b)(2)(B) (emphasis added). TSCA's definition includes not only "any study" of "any effect on health or the environment," but also "underlying information"; a non-exclusive list of types of scientific studies; and "any test performed" under TSCA. 15 U.S.C. § 2602(8).

As used in Section 14, 15 U.S.C. § 2613, "health and safety study" refers to the entire written report or document submitted to EPA. *Study*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/study ("a careful examination or analysis of a phenomenon, development, or question" and "the published report of such a study") (last visited November 7, 2023). Indeed, EPA admits as much, noting that information it redefines as "not part of a health and safety study" in fact includes "some types of information that may be included *in or with* a study document," Rule at 37,157 [JA__] (emphasis added), and characterizing some such information as "ancillary." *Id.* But Congress defined health and safety study expansively—"any study of any effect" including any "underlying information"—with no exclusion of pieces of information within the study documents, and TSCA is clear that the definition encompasses all information in and from health and safety studies. 15 U.S.C. § 2602(8).

Moreover, Congress enumerated two specific, narrow exceptions to this mandate, neither of which provides a basis for EPA's carveouts.[1] 15 U.S.C. § 2613(b)(2). EPA's newly created exceptions violate TSCA's plain language and structure by establishing exceptions beyond the statutorily specified ones. *Sierra Club v. EPA*, 705 F.3d 458, 468 (D.C. Cir. 2013) ("That Congress provided only

[1] Indeed, EPA did not rely on either statutory exemption as authority for its regulatory carveouts, nor did the Agency assert that they are relevant to its redefinition.

one exception to this monitoring requirement—a shorter monitoring period—suggests that Congress did not intend any other exceptions."). Thus, had Congress wanted to allow additional categories of information to be withheld from the public, including anything it deemed "ancillary," it could have done so seven years ago when it substantially amended TSCA.

Because the statute neither creates, nor authorizes EPA to create, exceptions to this definition beyond those explicitly provided in TSCA, the Agency's regulatory redefinition—amounting to a rewriting of TSCA—is unlawful. *Genus Med. Techs. LLC v. FDA*, 994 F.3d 631, 649 (D.C. Cir. 2021) (Pillard, J., concurring) (it is a "core administrative-law principle that an agency may not rewrite clear statutory terms to suit its own sense of how the statute should operate") (quoting *Util. Air Regulatory Grp. v. EPA*, 573 U.S. 302, 328 (2014)); *see also New York v. EPA*, 413 F.3d 3, 41 (D.C. Cir. 2005) (this Court has "consistently struck down administrative narrowing of clear statutory mandates") (quoting *Sierra Club v. EPA*, 129 F.3d 137, 140 (D.C. Cir. 1997)).

Further, EPA's carveouts undermine a key purpose of TSCA that was strengthened by the Lautenberg Act: the promotion of transparency of chemical information and public involvement in chemical regulation. *See, e.g.,* 15 U.S.C. §§ 2605(b)(4)(H), 2625(j). The statute's health and safety study provisions reflect

Congress' strong policy favoring the disclosure of information to accomplish these goals, limited only by the exceptions expressly provided in TSCA.

B. EPA failed to provide a reasoned basis for its redefinition and to address the value of the withheld information to the public

EPA itself states that it may not exclude from the definition of health and safety study any types of information that it cannot categorically determine are unnecessary to interpret the study. Rule at 37,157 [JA__]. Assuming *arguendo* that EPA could exclude any category of information from health and safety studies beyond what Congress permitted, by its own logic the Agency may not issue a rule blocking public access to an entire category of information in health and safety studies unless that information would be categorically unnecessary. EPA did not, however, provide a reasoned basis to counter commenters' establishment of the relevance and utility of the information that it did categorically exclude. To be lawful, EPA's action must not only be within the Agency's authority; it must also be the product of reasoned decisionmaking. *EDF v. FERC*, 2 F.4th 953, 967-68 (D.C. Cir. 2021). EPA has not satisfied this requirement.

The Rule's redefinition of health and safety studies will categorically shield from public disclosure numerous categories of information that are relevant to understanding a chemical's use and exposure pathways or the strength and reliability of the studies, including: product information, the identity of the company submitting the study, and the identity of the laboratory conducting the

study if it is affiliated with the submitting company. 40 C.F.R § 703.3. EPA blithely suggests that such 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 [JA__]. EPA's failure to respond specifically to commenters' concerns about the removal of this information from the public sphere, dismissing the concerns with a broad brush, along with the Agency's failure to provide reasonable support for narrowing Congress' statutory definition, is plainly arbitrary and capricious. Earthjustice Comments at 9-13 [JA__]; EDF Comments at 33-35 [JA__]; *Judulang v. Holder*, 565 U.S. 42, 52-53 (2011) (holding arbitrary and capricious an agency decision for failure to provide a "reasoned explanation").

First, EPA has redefined health and safety studies to exclude the identity of the company submitting the health and safety study, along with the laboratory performing the study when the laboratory is "part of or closely affiliated with the submitting company." 40 C.F.R § 703.3. Whether a company with a vested financial interest in the subject chemical is the submitter of the study is, in fact, directly relevant to assessing the study's reliability and objectivity and is therefore key information both for EPA and for groups like EDF and the broader public. For the same reason, the identity of a laboratory that is "closely affiliated with the company" can be key to gauging the study's reliability and objectivity.

The relevance of potential financial conflicts of interest in research is widely recognized, including by EPA. *See, e.g.*, EPA, *Science and Technology Policy Council Peer Review Handbook*, *4th Edition*, 62-63 (2015), https://www.epa.gov/sites/default/files/2020-08/documents/epa_peer_review_handbook_4th_edition.pdf (stating that sources of compensation, employment, and research funding must be inquired into to identify possible conflicts of interest or bias of potential peer reviewers appointed by EPA); National Research Council, *Review of EPA's Integrated Risk Information System (IRIS) Process*, 79 (2014) ("[f]unding sources should be considered in the risk-of-bias assessment conducted for systematic reviews [of the scientific evidence] that are part of an IRIS assessment"). Moreover, the public interest in information that would assist the public in assessing bias or conflicts of interest renders it disclosable under FOIA. *See, e.g.*, *Friends of Animals v. Bernhardt*, 15 F. 4th 1254, 1266 (10th Cir. 2021) (information relevant to "consistent favoritism or bias towards or influence by industries" was of legitimate public interest warranting disclosure of elephant skin import data by Fish and Wildlife Service).

Second, in addition to preventing the public from assessing a key aspect of studies' reliability and objectivity, EPA's categorical shielding of company identities conceals from the public information that can serve as a starting point to understand the uses of and potential exposures to the chemicals. Company

identities can provide insight into where the chemicals are made and released, how they are used, and what individuals or groups may be exposed. EDF Comments at 34-35 [JA__-__]. For example, knowledge of the identities, if traceable to the facilities making or using the subject chemicals, can potentially point to communities and environments that may be impacted by those chemicals. *Id*. In addition, public knowledge of the locations where submitting companies make or distribute products containing the studied chemical can shed light on potential sources of workers' and consumers' exposures.

EPA gave no meaningful response to the above arguments. It summarily rejected the idea that the public would need or could use such information to evaluate the reliability and objectivity of the study. EPA Response to Comments at 14 [JA__]. It also did not respond meaningfully to commenters' concerns that its carveouts will deny access to information that could help inform the public about potential chemical exposure. *Id.*

Third, EPA's exclusion of product information, 40 C.F.R. § 703.3(4), suffers from similar defects. Product information is relevant to understanding the potential for exposure to a chemical that is the subject of the study, including to consumers and workers making or using such products or the chemicals they contain. EDF Comments at 35 [JA__]. EPA gave no meaningful response to this point expressed by commenters, stating merely that "[t]hese types of information do not often

appear in study reports themselves …" EPA Response to Comments at 14, [JA__]. Of course, the fact that a certain type of information may not always appear in health and study reports is no justification for categorically denying, contrary to Congressional mandate, public access to such information in health and safety studies.

In summary, some of the categorically excluded information is valuable in evaluating whether a study is reliable and objective and in shedding light on potential exposure to the studied substance, such as through use or disposal, which is information that Congress intended the public to be able to glean from health and safety studies. EPA's failure to respond with any reasonable explanation for its exclusions demonstrates that, in addition to constituting a violation of TSCA's plain language, EPA's redefinition was arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 43 (1983) (holding that agency action is arbitrary and capricious where the agency fails to provide a reasonable explanation for its decision).

II. EPA unlawfully prevents access to chemical identities in documents submitted in new chemical applications

EPA's Rule violates TSCA because, after a chemical company brings a new chemical onto the market, the Rule does not require the company to substantiate or EPA to review the company's earlier claims—made in documents including health

and safety studies—that the chemical identity is confidential. 40 C.F.R. § 703.5(b)(5)(ii).

Under TSCA, when a company submits a new chemical application, it may claim as confidential the identity of its chemical anywhere it appears in that application, including any attachments, without having to substantiate those confidentiality claims and without EPA reviewing them. 15 U.S.C. § 2613(c)(2)(G). TSCA limits this provision to a discrete period of time: before the chemical is commercialized. *Id.* EPA's Rule, however, allows a company's confidentiality claims and redactions of the chemical's identity submitted with its new chemical application to remain in place indefinitely even after the chemical enters commercial production. 40 C.F.R. § 703.5(b)(5)(ii). Not only is this provision contrary to TSCA's plain text, it eliminates regulatory provisions without recognition and explanation, and will deprive the public of access to information key to understanding the health and environmental effects of new chemicals once they are on the market.

A. EPA violated TSCA by failing to require substantiation and review of confidentiality claims for chemical identity in documents submitted before the chemical's commercialization

EPA's Rule is contrary to the plain language of TSCA, which states that:

> …the following information shall not be subject to substantiation requirements …
>
> (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 [TSCA Section 5].

15 U.S.C. § 2613(c)(2)(G) (emphasis added). The phrase "prior to the date on which a chemical substance is first offered for commercial distribution" places a temporal limit on when and for how long substantiation is not required. This limitation means that, although substantiation for chemical identity claims in a new chemical application is not required during the period before commercialization, at the point of commercialization the claims become subject to TSCA's general substantiation and review requirements. 15 U.S.C. §§ 2613(g)(1)(A), 2613(c)(3); *Jimenez v. Quarterman*, 555 U.S. 113, 118 (2009) ("It is well established that, when the statutory language is plain, we must enforce it according to its terms."). But EPA has now effectively written the temporal limitation out of the statute and

rendered the substantiation and review exemption indefinite rather than temporary. 40 C.F.R. § 703.5(b)(5)(ii).

If Congress intended the exemption from substantiation and review for chemical identity CBI claims to be indefinite and determined solely by when documents are submitted, it would have said so. *Lozano* v. *Montoya Alvarez*, 572 U.S. 1, 16 (2014) ("Given that the drafters did not adopt that alternative, the natural implication is that they did not intend" to do so.). Rather than specifying that a specific chemical identity claim is exempt from substantiation "prior to" commercialization, Congress could have instructed that the claim is "permanently" exempt from substantiation "as long as the document is submitted prior to" commercialization, or something similar. It did not do so.

Alternatively, Congress could have left out the "prior to" phrase. In fact, this is what Congress did for all of the other exemptions from the substantiation requirement. The exemptions provided in subsections 14(c)(2)(A) through (F) are not time-limited because those provisions do not contain the "prior to" phrase. 15 U.S.C. § 2613(c)(2). Congress's "prior to [commercialization]" phrase in subsection 14(c)(2)(G) must be given effect. *TRW Inc.* v. *Andrews*, 534 U.S. 19, 31 (2001) ("a statute ought, upon the whole, to be so construed that, if it can be prevented, no clause" is rendered "superfluous, void, or insignificant.") (quoting *Duncan* v. *Walker*, 533 U. S. 167, 174 (2001)); *see also Young v. UPS*, 575 U.S.

206, 226 (2015). Thus, once a chemical is commercialized, EPA must require substantiation and review of all specific chemical identity CBI claims in all previously submitted documents associated with the substance.

B. EPA reversed longstanding regulations requiring substantiation and review without acknowledging or adequately explaining the change

For decades, EPA's regulations stated that a claim of confidentiality for a chemical identity, including one in a health and safety study, made without substantiation would only last until the chemical was commercialized—at which point the claim would then be subject to reassertion and substantiation. 40 C.F.R. § 720.90(b)(2) (2022) (repealed 2023); 40 C.F.R. § 720.85(b)(1) (2022) (repealed 2023). These regulations distinguished between claims made in documents submitted before commercialization and those in documents submitted at the time of commercialization. 40 C.F.R. § 720.90(b)(2) stated that CBI claims for specific chemical identity made specifically in health and safety documents had to be reasserted and substantiated "in conjunction with" more general claims for specific chemical identity made at the time of commercialization. Hence such a claim made in a health and safety study originally included in a new chemical application submitted before commercialization had to be *reasserted*, and for the first time substantiated, to be considered for continuation upon commercialization.

Before the Lautenberg Act, TSCA had no provisions requiring substantiation or EPA review of chemical identity CBI claims, or exempting them from such

requirements for limited periods. 15 U.S.C. § 2613 (2015). In 2016, Congress added to Section 14 language very similar to the provisions in 40 C.FR. § 720.90 and § 720.85 in effect at that time, stating that only "prior to the date on which a chemical substance is first offered for commercial distribution" a specific chemical identity CBI claim is not subject to substantiation. 15 U.S.C. § 2613(c)(2)(G). Congress also added language requiring EPA review as well as substantiation of any asserted (including reasserted) claims other than those designated under Section 14(c)(2). 15 U.S.C. § 2613(g)(1)(A). Hence any confidentiality claim for chemical identity in a health and safety study reasserted upon commercialization must be subject to both substantiation and review. Consistent with the Lautenberg Act, EPA could have carried forward into its Rule its previous requirement that chemical identity claims made earlier have to be reasserted and substantiated at the time of commercialization, making them subject to the 90-day EPA review that TSCA requires. EPA did not do so. Instead, EPA has deleted subsections 720.90 and 720.85 entirely and radically changed its approach.

EPA has inadequately justified this change. In response to EDF's comments on the deletion of subsection 720.90, EPA simply stated that it disagrees with EDF about subsection 14(c)(2)(G) and that EPA may not require substantiation and review of chemical identity claims in new chemical applications within TSCA's required review timeline. EPA Response to Comments at 49, [JA__]; *see also* Rule

at 37,162 [JA__]. However, any chemical identity claim asserted under subsection 14(c)(2)(G) in a new chemical application expires at the time of commercialization. EPA could have maintained its requirement under subsection 720.90(b)(2) that the claim must be reasserted upon commercialization. This reassertion, which would require substantiation and review, is when the 90-day review period would begin. And thus, requiring such substantiation and review would comply with TSCA's review timeline.

EPA's response also fails to address EDF's comment that EPA effectively transforms what Congress clearly intended to be a temporary exemption into an indefinite one. The end result is that, under EPA's Rule, the public will be denied access to specific chemical identities in all of the health and safety information submitted for hundreds of new chemicals per year. EPA, *Premanufacture Notices (PMNs) and Significant New Use Notices (SNUNs) Table*, https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and (last visited November 7, 2023).

EPA's response to EDF's comments on subsection 720.85's deletion is similarly inadequate. EPA justified this change by claiming, contrary to the actual statutory language, that subsection 703.5(b)(5)(ii)(A) is a "simple restatement" of section 14(c)(2)(G). EPA Response to Comments at 48 [JA__].

An agency may, of course, change its mind. *FCC v. Fox TV Stations, Inc.*, 556 U.S. 502, 515 (2009). But it cannot do so without acknowledging that it is changing its mind, explaining why, and providing "reasoned analysis indicating that prior policies and standard are being deliberately changed, not casually ignored." *Fairless Energy, LLC v. FERC*, 77 F.4th 1140, 1146-47 (D.C. Cir. 2023) (quoting *E. Ky. Power Coop., Inc. v. FERC*, 489 F.3d 1299, 1306 (D.C. Cir. 2007)); *see also FCC v. Fox TV Stations, Inc.*, 516 U.S. at 515-16. EPA did not satisfy this standard, and its removal of subsections 720.90 and 720.85 is arbitrary and capricious. *Encino Motorcars, LLC v. Navarro*, 579 U.S. at 222 (holding arbitrary and capricious an agency's failure to acknowledge and adequately explain its changed regulation).

Access to documents associated with new chemical applications that specifically identify a chemical substance, such as health and safety studies, allows EDF, and the broader public, to make connections between documents characterizing the risks a chemical may pose and the manner in which it will be commercialized. As EPA has stated,

> Chemical identities in particular constitute basic information that helps the public to place risk information in context. Making public chemical identities in health and safety studies whose confidentiality is precluded by TSCA will support the Agency's mission.

EPA, *Claims of Confidentiality: Certain Chemical Identities Contained in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the*

Toxic Substances Control Act, 75 Fed. Reg. 29,754, 29,757 (May 27, 2010). For example, when a plant begins using a new chemical as part of its manufacturing process, workers or advocates concerned about workers' exposure to this chemical may search for health and safety information about it. Where the chemical identity remains concealed in the studies that the company submitted with its application to make the new chemical, workers and the broader public would be blocked from connecting available health and safety studies to the chemical to which they may be exposed. In contrast, as Congress contemplated, access to such studies or other documents that identify the subject chemical (which the public could obtain as a result of EPA review and denial of chemical identity claims subject to substantiation) could inform advocacy for health-protective regulations on the chemical's production or use, and generally about EPA's administration of TSCA's new chemicals program. 75 Fed. Reg. at 29,756 ("EPA believes that Congress generally intended for the public to be able to know the identities of chemical substances for which health and safety studies have been submitted."); Hampshire Research Associates, Inc., *Influence of CBI Requirements on TSCA Implementation*, 16 (March 1992), https://www.regulations.gov/document/EPA-HQ-OPPT-2002-0054-0074 (demonstrating that confidentiality claims are regularly withdrawn or found invalid when submitters are required to substantiate or defend the claims).

EPA itself recognizes that knowledge of the chemical identity in a health and safety study can be necessary to interpret that study. EPA Response to Comments at 13 [JA__]. But EPA has failed to consider the negative impacts that its new provision will have on the public's ability to make use of information like health and safety studies, even after such chemicals are in commerce. EPA's action is therefore arbitrary and capricious. *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. at 43 (holding that agency rules are arbitrary and capricious where an Agency fails to consider an important aspect of the problem).

Further, EPA fails to acknowledge that the permissible bases for confidentiality of chemical identity in a new chemical application can differ from those pertaining to a manufacture notice. Requiring reassertion, substantiation, and review of chemical identity claims in new chemical application documents once a chemical enters commerce would require EPA to determine whether each such claim is warranted in the specific context in which it was asserted. This context may differ significantly from the basis for masking a chemical's identity in a manufacture notice, where the relevant question is whether competitive harm would likely result from public knowledge that a chemical is in U.S. commerce. 40 C.F.R. § 703.5(b)(4)(i). For example, if such a claim had been asserted in a health and safety study submitted pre-manufacture, the information would not be protected from disclosure unless it satisfied one of the two narrow exceptions in

TSCA Section 14(b)(2). 15 U.S.C. § 2613(b)(2). Thus, EPA's review of chemical identity claims in a manufacture notice context is not equivalent to review of those claims, for the same chemical, in a new chemical application context. EPA's failure to consider the importance of chemical identities for increasing public understanding and opportunities for advocacy, as well as its failure to adequately explain its replacement of prior provisions requiring reassertion of chemical identity claims, makes its promulgation of subsection 703.5(b)(5)(ii) arbitrary and capricious.

III. EPA's Rule improperly treats as discretionary its mandatory duties under TSCA

EPA's Rule gives the Agency discretion to grant CBI claims even where they do not meet TSCA's minimum requirements, and further gives EPA discretion to not publish information where TSCA requires publication. In some cases, the Agency has replaced provisions mandating disclosure with provisions creating discretion—and it has not adequately explained these changes.

A. EPA's Rule allows unwarranted approval of confidentiality claims and the withholding of information to which the public is entitled under TSCA

EPA has given itself discretion that TSCA does not allow. First, the Rule provides that a submitter's failure to remedy a deficiency in a confidentiality claim means only that EPA "may deny" the CBI claim. 40 C.F.R. § 703.5(e)(2). But TSCA *requires* EPA to deny such claims. Specifically, Section 14 lays out the

requirements for the assertion of a valid CBI claim and requires EPA to approve or deny claims depending on whether the requirements have been met. 15 U.S.C. §§ 2613(c), 2613(g)(1). A failure to remedy a deficiency in a confidentiality claim means that the claim remains deficient, and therefore invalid, for failing to meet Section 14(c)'s requirements for a valid claim. 15 U.S.C. § 2613(c). Under this statutory scheme, EPA has no discretion to approve a CBI claim that fails to meet the statutory requirements.

EPA also created two provisions that give it discretion to withhold information from the public when the submitter fails to meet TSCA's clear requirements for confidentiality. 40 C.F.R. § 703.8(d) provides that, after EPA requests additional substantiation when reviewing a claim under Section 14(f), but the company fails to provide that substantiation, EPA will treat the claim as waived but only "may make" the information public.[2] 40 C.F.R. § 703.5 provides that if no CBI claim accompanies a document submitted to EPA pursuant to a TSCA requirement, the "information in or referred to in that submission *may* be made available to the public." (emphasis added). However, TSCA requires disclosure. As stated above, Section 14 lays out the requirements for protecting information from disclosure and requires EPA to determine whether a given piece of

[2] Section 14(f) allows or requires EPA to require submitters to reassert or resubstantiate CBI claims and to review such claims in specified cases, such as when a chemical is designated a high-priority substance. 15 U.S.C. § 2613(f).

information qualifies for protection. Subsection 14(g)(2) generally requires EPA to inform a submitter when the Agency has denied a CBI claim and to inform the submitter of EPA's intent to disclose the information. 15 U.S.C. § 2613(g)(2). Subsection 14(g)(2)(B) sets limits on this disclosure, requiring EPA not to disclose information until 30 days after notifying the submitter, except as provided in subsection 14(g)(2)(C). *Id*. at § 2613(g)(2)(B). All of these requirements would be nonsensical if EPA was not required to deny CBI protection to inadequate claims and to publicly disclose the information that is not afforded CBI protection. Failure to assert or adequately substantiate claims should result in certain disclosure under these mandatory provisions, not merely *possible* disclosure, because there is no legal basis on which to keep information from the public.

Thus, in these new regulatory provisions, EPA should have stated that it "shall" or "will" deny claims and provide information to the public, rather than stating that it "may" do so. The Supreme Court has held that the use of "shall" imposes "discretionless obligations" as compared to the use of the "permissive" word "may." *Lopez v. Davis*, 531 U.S. 230, 241-42 (2001). It has further stated that the word "may" "implies discretion" while "shall" connotes a requirement. *Kingdomware Techs., Inc. v. United States*, 579 U.S. 162, 171 (2016). This Court has also emphasized that "may" is generally a discretionary word. *Sierra Club & Valley Watch, Inc. v. Jackson*, 648 F.3d 848, 856 (D.C. Cir. 2017) ("[W]hen a

statute 'uses both "may" and "shall," the normal inference is that each is used in its usual sense—the one act being permissive, the other mandatory.'") (citations omitted).

TSCA's legislative history further emphasizes the requirement that EPA make publicly available information that does not qualify for confidentiality. The Committee Report accompanying the version of the Lautenberg Act passed by the Senate in 2015 stated:

> In general, it is the Committee's intent to balance the need for protection from disclosure for information qualifying under [trade secret protection] with the needs to ensure access to such information under appropriate conditions by those who need it to perform their duties, and to *maximize public availability* of health and environmental information relating to chemical substances in commerce.

S. Rep. No. 114-67, at 21 (2015) (emphasis added). This same interest in maximizing public availability motivated the passage of the final version of the Lautenberg Act. In an analysis issued upon Senate passage of the 2016 version of the bill, which became law, Democratic Senators stated:

> Because EPA informed Senate negotiators that its practice is to promptly make public information that is no longer protected against disclosure, we see no difference or distinction in meaning between the language in S. 697 as passed and the Frank R. Lautenberg Chemical Safety for the 21st Century Act and expect EPA to continue its current practice of affirmatively making public information that is not or no longer protected from disclosure as expeditiously as possible.

162 Cong. Rec. 7985 (2016).

EPA itself has stated that "[p]art of the Agency's mission is to promote public understanding of potential risks by providing understandable, accessible and complete information on potential chemical risks to the broadest audience possible." EPA, *Claims of Confidentiality of Certain Chemical Identities Submitted Under Section 8(e) of the Toxic Substances Control Act*, 75 Fed. Reg. 3462, 3463 (Jan. 21, 2010).

Additionally, under the Freedom of Information Act ("FOIA"), disclosure is mandated when a valid claim for protection is not established. 5 U.S.C. §§ 552(a), 552(b). This Court has acknowledged that confidentiality protection is narrower under TSCA than it is under FOIA. *Envtl. Integrity Project v. EPA*, 864 F.3d 648, 649 (D.C. Cir. 2017) (noting that TSCA's narrower confidential business information provisions supersede the broader trade secret protections provided by FOIA exemption 4). It follows that where FOIA requires that information ineligible for protection from disclosure must be disclosed, TSCA must also be interpreted to require disclosure where information is not protected.

The Agency denied that these regulations enlarge its discretion, and did not provide reasons for using discretionary language. EPA acknowledged EDF's comments that subsections 703.5 and 703.8(d) did not comport with EPA's obligations to deny CBI claims where they are not supported and to provide information to the public where it is not protected by a proper CBI claim. EDF

Comments at 23-26 [JA__]; Rule at 37,160 [JA__]; EPA Response to Comments at 41, 46 [JA__]. However, the Agency did not adequately address these concerns. For example, in replying to comments on its use of permissive language like "may deny," the Agency stated only that:

> [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 it were withdrawn, or the submitter made a persuasive argument that it was exempt from substantiation requirements). Elsewhere, "may be" is used when discussing public disclosure. Here it is not intended to suggest that disclosure is in doubt when the information is requested, but rather to provide EPA with discretion and flexibility on the timing for proactively or unilaterally disclosing data, particularly when there is little or no evident demand for the information.

EPA Response to Comments at 41 [JA__].[3] This fails to acknowledge or address the fact that EPA's approach is contrary to TSCA by failing to make disclosure mandatory and improperly enlarging the Agency's discretion.

Because EPA has essentially failed to offer an explanation (or at the very least has offered an explanation that is not only inadequate but is also counter to the evidence), the Agency's provisions granting itself impermissible discretion are arbitrary and capricious as well as contrary to TSCA.

[3] To the extent that EPA means that a request from a member of the public is a precondition for public disclosure, such a requirement exists nowhere in TSCA except in the case of a FOIA request governed by Section 14(f)(2)(A). 15 U.S.C. § 2613(f)(2)(A).

B. EPA replaced mandatory provisions requiring denial of improper claims and public disclosure of information with discretionary provisions, without adequate explanation

With its Rule, EPA weakened numerous CBI provisions, replacing regulatory statements that EPA "will" deny confidentiality claims or disclose information with statements that the Agency "may" take these actions.

First, EPA's Rule provides that if a submitter does not include a CBI claim with a document submitted pursuant to a TSCA requirement, then the "information in or referred to in that submission *may* be made available to the public." 40 C.F.R. § 703.5 (emphasis added). This change replaced numerous provisions that mandated disclosure in this circumstance, such as: "[i]f no claim of confidentiality accompanies a document at the time it is submitted to EPA, the document *will* be placed in an open file available to the public without further notice to the respondent." 40 C.F.R. § 716.55(c) (2022) (repealed 2023) (emphasis added); *see also* 40 C.F.R. § 704.7(b) (2022) (repealed 2023); 40 C.F.R. § 717.19(b) (2022) (repealed 2023); 40 C.F.R. § 790.7(a) (2022) (repealed 2023). Second, while the Rule provides that companies must submit second, public copies of their documents containing redactions of information claimed as confidential, it does not state that failure to do so will result in EPA making the first copy public. In contrast, EPA previously provided that "Failure to furnish a second copy of the notice when information is claimed as confidential in the first copy will be

considered a presumptive waiver of the claim of confidentiality. … Failure to submit the second copy *will* cause EPA to place the first copy in the public file." 40 C.F.R. § 704.7(c)(4) (2022) (repealed 2023) (emphasis added).

Like "shall," the word "will" constitutes mandatory language." Merriam-Webster includes the following definitions for "will": "[a word] —used to express futurity" or "[a word] used to express a command, exhortation, or injunction." *Will*, Merriam-Webster Online Dictionary, https://www.merriam-webster.com/dictionary/will (last visited November 7, 2023). Courts in this Circuit have interpreted "will" as mandatory language. *See Wilderness Soc'y v. Norton*, 434 F.3d 584, 595 (D.C. Cir. 2006) (treating "will" and "must" as "mandatory language"); *Sierra Club v. Leavitt*, 355 F. Supp. 2d 544, 551 (D.D.C. 2005) (a regulation that states "the Administrator will take final action [on a proposal]" "uses mandatory language"); *Chiang v. Kempthorne*, 503 F. Supp. 2d 343, 350 (D.D.C. 2007) (holding that guidelines stating that an agency "will not issue orders to pay or perform" and "will grant appeals" are mandatory and "definitive pronouncements"). By replacing the above provisions containing the mandatory "will" with the discretionary "may," EPA has changed its regulations in a way that leaves it discretion to not take actions that it previously obligated itself to take. The Agency must acknowledge and provide adequate justification for that change. *Encino Motorcars, LLC*, 579 U.S. at 221; *FCC v. Fox TV Stations, Inc.*, 556 U.S.

at 515; *Fairless Energy, LLC*, 77 F.4th at 1146-47. Here, EPA has neither acknowledged nor adequately explained these changes.

In comments to EPA, EDF stated that the proposed "equivocal language would replace much more definitive language already in EPA's regulations," and detailed the relevant provisions. EDF Comments at 17 [JA__]. The Agency responded only that the preexisting provisions "do not fully implement the new requirements under section 14 and have a good deal of variation in their requirements" and that the regulations previously required notice to submitters where none is required now. EPA Response to Comments at 46 [JA__]. This response ignores the thrust of EDF's comments—that the Agency replaced requirements with equivocation. In promulgating these provisions, EPA has violated the requirement that it acknowledge and explain when it changes its regulations, which will result in potential withholding of information that must be released to the public.

CONCLUSION AND REQUESTED RELIEF

Vacatur is the normal remedy when a rule is found unlawful. *Am. Pub. Gas Ass'n v. United States DOE*, 72 F.4th 1324, 1342 (D.C. Cir. 2023). Exceptions to that rule—a likelihood that EPA could address the provisions' deficiencies on remand without vacatur or that vacatur would pose significant disruption—do not apply here. *Id.* Thus, in light of the legal shortfalls of the Rule's challenged

provisions, described above, vacatur is required. *Id.; see also Cboe Futures Exch., LLC v. SEC*, 77 F.4th 971, 982 (D.C. Cir. 2023).

The Court may vacate just the challenged provisions, which are severable from the other regulatory provisions in the Rule. "Regulations—like statutes—are presumptively severable: If parts of a regulation are invalid and other parts are not, we set aside only the invalid parts unless the remaining ones cannot operate by themselves or unless the agency manifests an intent for the entire package to rise or fall together." *Bd. of Cty. Comm'rs of Weld Cty. v. EPA*, 72 F.4th 284, 296 (D.C. Cir. 2023).

EDF therefore respectfully requests that the Court grant the petition for review, vacating the challenged provisions and instructing the Agency to issue regulations consistent with the Court's decision. 15 U.S.C. § 2618(c).

Respectfully submitted,

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/s/ Samantha Liskow

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CERTIFICATES OF COMPLIANCE AND SERVICE

I certify that this brief complies with Federal Rule of Appellate Procedure 32(a)(5) and (6) because it has been prepared in 14-point Times New Roman, a proportionally spaced font.

I also certify that this brief complies with the Court's September 26, 2023 order because by Microsoft Word's count, it contains 8,879 words, excluding the parts of the brief exempted by Federal Rule of Appellate Procedure 32(f) and D.C. Circuit Rule 33(e)(1).

Finally, I certify that today I electronically filed this Initial Brief of Petitioner Environmental Defense Fund on all registered counsel through the Electronic Case Filing (ECF) system for the United States Court of Appeals for the D.C. Circuit.

/s/ Samantha Liskow
Samantha Liskow

DATED: November 8, 2023