ORAL ARGUMENT HAS NOT YET BEEN SCHEDULED

No. 17-1201

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

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ENVIRONMENTAL DEFENSE FUND,
Petitioner,

v.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY; AND SCOTT PRUITT, ADMINISTRATOR, UNITED STATES ENVIRONMENTAL PROTECTION AGENCY,
Respondents,

AMERICAN CHEMISTRY COUNCIL; et al.,
Intervenors for Respondents.

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PETITION FOR REVIEW OF RULE OF U.S. ENVIRONMENTAL PROTECTION AGENCY, "TSCA INVENTORY NOTIFICATION (ACTIVE-INACTIVE) REQUIREMENTS," 82 FED. REG. 37,520 (AUG. 11, 2017)

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# PETITIONER ENVIRONMENTAL DEFENSE FUND'S REPLY BRIEF

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**Cases:**



* Authorities upon which we chiefly rely are marked with asterisks.

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## GLOSSARY

| | |
|---|---|
| APA | Administrative Procedure Act |
| CBI | Confidential Business Information |
| EDF | Environmental Defense Fund |
| EPA | Environmental Protection Agency |
| FOIA | Freedom of Information Act |
| TSCA | Toxic Substances Control Act |

## INTRODUCTION

"[W]hen Congress acts to amend a statute, we presume it intends its amendment to have real and substantial effect." *Pub. Citizen, Inc. v. HHS*, 332 F.3d 654, 671 (D.C. Cir. 2003). Here Congress thoroughly amended TSCA §§8 and 14 governing the Inventory and confidentiality claims to provide the public with more information about chemicals in commerce, so that the American people can study chemicals' uses, exposures, and health and environmental effects. EDF Br. 23-28. Congress sought to change EPA's prior, failed practices, EDF. Br. 6-7, and EPA cannot ignore that direction simply because EPA prefers business as usual under its preexisting regulations and practice. Congress struck a new balance between the public's right to know and industry's interests in confidentiality, and EDF seeks to enforce that balance. In contrast, EPA repeatedly refuses to give meaning to Congress's words. But "the fact that EPA thinks a statute would work better if tweaked does not give EPA the right to amend the statute." *Ams. for Clean Energy v. EPA*, 864 F.3d 691, 712 (D.C. Cir. 2017).

Additionally, "an agency's action must be upheld, if at all, on the basis articulated by the agency itself." *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 50 (1983). EPA repeatedly presents *post hoc* rationales for its action that appear nowhere in the administrative record. On this basis alone, this Court should grant the petition.

## SUMMARY OF ARGUMENT

*First*, under the plain language of "maintain" and "existing claim," a person cannot "maintain an existing claim" if the person never asserted the claim before. 15 U.S.C. §2607(b)(4)(B)(ii). EPA has impermissibly read the word "existing" out of TSCA §8. And EPA does not defend the rationale for its interpretation that appears in the administrative record.

*Second*, TSCA requires that confidential information must be "not readily discoverable through reverse engineering." *Id.* §2613(c)(1)(B)(iv). EPA failed to incorporate this requirement into the substantive standard for reviewing confidentiality claims and EPA failed to require substantiation of this criterion. EDF has standing to challenge EPA's failure to even consider this issue.

*Third*, TSCA §§14 and 26(j) impose numerous procedural requirements on EPA when processing confidentiality claims, and EPA failed to incorporate those requirements into this rule. As a result, EPA has systematically violated those requirements in its implementation, injuring EDF and the public.

*Fourth*, TSCA §8(b)(7)(B) requires that EPA place unique identifiers and other information on the Inventory for every active confidential chemical "for which a claim of confidentiality was received." *Id.* §2607(b)(7)(B). EPA failed to address this duty when developing the rule governing the Inventory, and EPA's *post hoc* rationale for postponing consideration of this duty fails on its own terms.

*Fifth*, the only statutory basis for an exemption from TSCA requirements for export-only chemicals appears in TSCA §12, and TSCA §12 expressly does not exempt export-only chemicals from reporting under TSCA §8. Thus, EPA should have mandated their reporting.

## ARGUMENT

### I. The final rule illegally allows manufacturers and processors to assert new claims.

#### A. A person cannot "*maintain* an *existing claim*" if the person (or a predecessor-in-interest) has never made the claim before.

EPA and Intervenors (collectively, Respondents) never grapple with the key statutory language of TSCA §8(b)(4)(B)(ii). Instead, Respondents fixate on the section's inclusion of the adjective "any" and an indefinite article "an," but statutory interpretation turns upon verbs and nouns as well. TSCA §8(b)(4)(B)(ii) applies to "any manufacturer or processor of a chemical substance on the confidential portion of the [Inventory]," but only a few words later, the section defines what those persons may do. They may "seek[] to *maintain* an *existing claim*" by submitting a request. 15 U.S.C. §2607(b)(4)(B)(ii) (emphases added). Under the plain language of "maintain" and "existing claim," a person cannot "maintain an existing claim" if the person never asserted the claim before. EDF Br. 31-32. "Claim" means "a demand or request for something considered *one's* due *** a right or title to something." *Oxford American Dictionary* 318 (3d ed.

2010). Respondents present no plain language account of how a person asserting a claim for the first time is "maintain[ing] an *existing claim*." Respondents provide no meaning to "existing" or "claim."

EDF previously established that confidentiality claims are "person-specific" under TSCA's provisions, the historical regulations, and the broader precedent governing such claims. EDF Br. 16, 32-36. In their Briefs, Respondents never dispute that, by their nature, confidentiality claims are generally "person-specific" under TSCA or the precedent governing such claims, apparently because it is indisputable (Intervenors even concede (Br. 13) claims under TSCA §14 are "person-specific.").[1] Thus, a person asserting a claim for the first time is making a "new" claim; the person is neither maintaining an "existing claim" nor making the same claim a prior person asserted.

Rather than offering an interpretation of the words Congress included in the statute, Respondents simply read the word "existing" out of the statute entirely, violating a core tenant of statutory construction. EPA even contends that whether confidentiality claims are "'new' is a semantic matter with no legal significance." EPA Br. 22 n.1; EPA Br. 25 (acknowledging that EPA's interpretation allows

[1] Intervenors suggest that claims under TSCA §8 are different. But TSCA §8 repeatedly states that its confidentiality claims are all "pursuant to section 14." 15 U.S.C. §2607(b)(4)(B)(ii); EDF Br. 44. That Congress did not reiterate person-specific language in TSCA §8(b)(4)(B)(ii) does not change the nature of the claims, particularly when that provision expressly incorporates TSCA §14.

"new claims"). But Congress limited the TSCA §8(b)(4)(B)(ii) process to "existing claim[s]," so it *is* legally significant. New claims are not allowed through this process.

EPA seeks (Br. 21) to support its atextual reading of the statute by reference to its pre-Lautenberg regulations regarding affected businesses, where EPA would allow certain affected businesses to assert new claims in certain circumstances. These regulations confirm that EPA's regulations did not allow one business to rely on another business's claim; the affected business had to make a new, independent claim.

Congress could have easily created the scheme Respondents prefer by requiring "any manufacturer or processor of a chemical substance on the confidential portion of the [Inventory] that [seeks to continue] protection against disclosure *** to submit a notice *** that [asserts such a claim]." Numerous alternative formulations were available. But Congress chose not to sweep so broadly, only allowing persons to request "to maintain an existing claim." 15 U.S.C. §2607(b)(4)(B)(ii). EPA asserts policy reasons for wanting a different approach (EPA shifts to policy arguments by the second page of its argument section), but that desire is insufficient to rewrite the statute Congress enacted, and Respondents have never presented any coherent textual theory to justify EPA's approach.

In a *post hoc* argument, EPA contends (Br. 22) that its interpretation is reasonable because otherwise TSCA §8(b)(8) would allegedly be superfluous. But under the correct interpretation of that provision (which EPA adopted in the rule), it still holds significant meaning. TSCA §8(b)(8) forecloses any assertion of confidentiality claims under *either* TSCA §8 *or* §14 for chemicals on the public portion of the Inventory, through *any* process. *See* 15 U.S.C. §2607(b)(8). EPA adopted this interpretation of TSCA §8(b)(8) by allowing confidentiality requests "only" for chemicals "on the confidential portion of the Inventory." EPA-HQ-OPPT-2016-0426-0070 p.24 (JA:146) (40 C.F.R. §710.37(a)); *see* EPA-HQ-OPPT-2016-0426-0086 p.53 (JA:179) (linking this language to TSCA §8(b)(8)).

"Congress had good reason to take a belt-and-suspenders approach" in drafting TSCA §8(b)(8) and reasonably included a provision that partially "overlap[s]" with the limitation of TSCA §8(b)(4)(B)(ii) to existing claims. *Mercy Hosp., Inc. v. Burwell*, 206 F. Supp. 3d 93, 98 (D.D.C. 2016). With TSCA §8(b)(8), Congress sought "to remove any doubt" about chemicals on the public portion of the Inventory. *Id.* (quoting *Ali v. Fed. Bureau of Prisons*, 552 U.S. 214, 226 (2008)). Indeed, TSCA §8(b)(8) states a logical tautology: the specific identities of chemicals already published on the public Inventory are widely known and therefore could not logically be claimed confidential. Congress codified this principle out of an abundance of caution given the history of EPA's approach to

confidentiality under TSCA (EDF Br. 6-7) and of frivolous confidentiality claims for publicly known chemicals. By its very nature, TSCA §8(b)(8) is an example of Congress codifying a provision, "in Macbeth's words, 'to make assurance double sure.'" *Fla. Health Scis. Ctr., Inc. v. Sec'y of HHS*, 830 F.3d 515, 520 (D.C. Cir. 2016). That such a provision has some redundancy with other provisions of the Act is no surprise.

Respondents' primary theory for their interpretation is that Congress could not have meant to limit the scope of §8(b)(4)(B)(ii) to "existing claims," *i.e.*, those asserted by persons who have previously claimed confidentiality for a chemical identity. But the limitation makes sense in light of the issue Congress sought to address. The question here is whether EPA should publicly share the specific chemical identities of chemicals already in commerce that persons submitted to EPA before Congress amended TSCA. Congress reasonably chose to allow *any* manufacturer or processor who provided such information to EPA in the past and made a claim of confidentiality to seek to preserve that confidentiality. No prior claims are voided under this theory.

Respondents' position is that Congress must have intended for persons who had no role in providing the information about specific chemical identity to EPA to have an opportunity now to claim that information confidential. But as those persons never provided that information to EPA, Congress could reasonably

conclude that they have no right to use this process to block public access to the information provided by others; they have no such right under the general law governing confidential information or trade secrets. *See* EDF Br. 36; EPA Br. 20. Moreover, based on its concern for those persons, EPA insists that it must also allow persons who previously waived their confidentiality claims a renewed opportunity to use this process to assert confidentiality. Congress could reasonably believe differently.

### B. The rationale provided with the rule is false and thus does not justify EPA's broad exemption.

In the final rule, EPA rationalized allowing new confidentiality claims from *all* manufacturers and processors under §8(b)(4)(B)(ii) by stating that "when such persons did not *originally* report that chemical identity to EPA," they "*therefore* were not in a position to assert a CBI claim for that chemical identity." EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:130) (emphases added). Thus, EPA's articulated rationale was that only the original submitter had an opportunity to make a confidentiality claim and therefore, EPA needed to allow any manufacturer or processor to use this process to assert a new claim for confidentiality.

EDF's Opening Brief established that EPA's articulated premise was factually and legally false. Br. 37-42. And EPA does not attempt to defend the broad rationale it articulated in its administrative record. *Compare* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:130), *with* EPA Br. 27-30. As a result, EPA's

reasoning is arbitrary and capricious. "Reliance on facts that an agency knows are false at the time it relies on them is the essence of arbitrary and capricious decisionmaking." *Animal Legal Def. Fund, Inc. v. Perdue*, 872 F.3d 602, 619 (D.C. Cir. 2017). Instead, EPA presents (Br. 27) a new, narrower rationale for its decision, but in assessing the agency's interpretation, this Court "look[s] to what the agency said at the time of the rulemaking—not to its lawyers' post-hoc rationalizations." *Council for Urological Interests v. Burwell*, 790 F.3d 212, 222 (D.C. Cir. 2015).

In contrast to EPA, Intervenors baldly contend (Br. 1) that EPA's pre-Lautenberg regulations allowed persons to rely on the prior confidentiality claims of others, but Intervenors provide no citation for this assertion and it is false. Where Intervenors provide citations, the regulations do *not* create any right for a person to rely on a prior submitter's confidentiality claim. *See, e.g.*, Intervenor Br. 14. Since the 1970s, if a person notified EPA about a chemical, then that person had to assert a confidentiality claim contemporaneously or risk waiving the claim. 40 C.F.R. §2.203(b)-(c); 41 Fed. Reg. 36,902, 36,907 (Sept. 1, 1976); *see also, e.g.*, 48 Fed. Reg. 21,722, 21,751 (May 13, 1983). For example, nothing in the regulations stated that submitters of notices of *bona fide* intent did not need to submit confidentiality claims if they sought protection against disclosure. The regulations provided that "(a) [a] person may assert a claim of confidentiality for

*any* information which he or she submits to EPA under this part" and "(b) *[a]ny* claim of confidentiality must accompany the information when it is submitted to EPA." 40 C.F.R. §720.80(a)-(b) (emphases added). The existing legal structure did not authorize reliance on other people's confidentiality claims. And the administrative record did not justify the rule based on a "reliance" interest under the prior regulations.

In a lengthy *post hoc* rationalization, EPA now submits—much more narrowly than its original rationale—that "some" manufacturers and processors may have previously had limited opportunity to assert claims before EPA. EPA Br. 27. This rationale is not only *post hoc*, it is wrong. First of all, any person could have informed EPA of specific chemical identities in commerce and asserted a confidentiality claim in the past; none were barred.

Even if true, EPA's new rationale does not justify EPA's broad exemption allowing *anyone* to assert confidentiality claims, irrespective of whether they had a prior opportunity to do so. As EDF already acknowledged, allowing claims in the limited circumstances of certain preexisting relationships, such as mergers and acquisitions, fits the statutory text—allowing persons to "maintain an existing claim." Other narrow circumstances might also fit within the meaning of "existing claim," and on remand, EPA may develop a reasonable interpretation of those words that covers some of the relationships described in Respondents' Briefs (EPA

Br. 28-29; Intervenor Br. 17-19). But these narrow circumstances do not justify EPA's decision to allow any and all persons to assert new claims based on claims asserted by any and all other persons to which they have no relationship.

As for processors, EPA has broad authority to require reporting from processors under TSCA §8. 15 U.S.C. §2607(a). As a practical matter, processors would have reported specific chemical identities and made confidentiality claims when, for example, reporting on "substantial risks" under TSCA §8(e) or significant new uses under TSCA §5. *See id.* §§2607(e), 2604(a)(1)(A)(ii). Contrary to EPA's *post-hoc* rationale (Br. 29-30), Congress allowed processors to "maintain an existing claim" because many processors have existing claims to maintain.

While EPA asserts (Br. 27) that EDF failed to raise part of its argument earlier, EDF raised the basic issue in comments. EPA-HQ-OPPT-2016-0426-0064 pp.13-14 (JA:106-107). And EPA did not clearly articulate its theory that only the original submitter had an opportunity to assert confidentiality claims until the final rule. *Compare* EPA-HQ-OPPT-2016-0426-0070 p.8 (JA:130), *with* EPA-HQ-OPPT-2016-0426-0001 p.7 (JA:007). EDF never had an opportunity to rebut a rationale that EPA only presented in the final rule. *See CSX Transp., Inc. v. Surface Transp. Bd.*, 584 F.3d 1076, 1079 (D.C. Cir. 2009). Furthermore, EPA "retains a duty to examine key assumptions as part of its affirmative burden ***

and therefore EPA must justify that assumption even if no one objects to it during the comment period." *NRDC v. EPA*, 755 F.3d 1010, 1023 (D.C. Cir. 2014). Here, EPA does not defend the broad rationale articulated in the final rule.

*Finally*, EDF acknowledged that new claims may be permissible under TSCA §14 because TSCA §14 provides the sole mechanism for new claims. EPA and Intervenors criticize this approach in a *post-hoc* set of arguments, but neither rules out this possibility either. EPA Br. 30-31; Intervenors Br. 19-21. They refuse to grapple with the problems presented by their position: EPA will receive confidentiality claims under TSCA §14 through other reporting requirements—such as the new chemicals program and chemical data reporting rule—for chemicals already on the confidential portion of the Inventory during the review period. Will EPA reject some or all of these claims, as suggested by the theory in its Brief (pp.30-31)? Since EPA refused to address this important aspect of the problem in the rulemaking, it is impossible to know.

In sum, EPA's decision rests on a rationale that EPA does not defend and fails to consider several important aspects of the problem; it is arbitrary and capricious.

## II. The final rule violates the substantive requirements of TSCA §14.

### A. TSCA requires that confidential information must be "not readily discoverable through reverse engineering."

Prior to the Lautenberg Act, public disclosure of information under TSCA incorporated the substantive confidentiality standard of FOIA Exemption 4 with a few exceptions. Pub. L. No. 94-469, §14, 90 Stat. 2034 (1976). With the Lautenberg Act, Congress revamped the requirements for confidentiality claims under TSCA §14 and required confidentiality claimants to meet the requirements of FOIA Exemption 4 "*and* *** the requirements of subsection (c)." 15 U.S.C. §2613(a) (emphasis added). EPA's *post hoc* assertion (Br. 10, 31-32) that TSCA §14(a) simply incorporates the substantive requirements of FOIA Exemption 4 is flatly incorrect. *See Loving v. IRS*, 742 F.3d 1013, 1019 (D.C. Cir. 2014) ("[T]he statute uses the conjunctive 'and'—not the disjunctive 'or'—when listing the various requirements, a strong indication that Congress did not intend the requirements as alternatives.").

TSCA §14(c) is titled "[r]equirements for confidentiality claims." 15 U.S.C. §2613(c). While many of these requirements are procedural, some are also substantive. TSCA §14(c)(1)(B) requires that claimants assert that they meet four criteria, including that they have "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." *Id.* §2613(c)(1)(B)(iv). This requirement is both a procedural obligation and a substantive standard for

claims. Congress intended that EPA would consider whether the information meets all four criteria when determining whether to grant a confidentiality claim under TSCA §14. *Cf. Dithiocarbamate Task Force v. EPA*, 98 F.3d 1394, 1399 (D.C. Cir. 1996) (finding agency decision arbitrary when agency failed to consider certain factors in list).

Thus, EDF challenges the substantive standard of 40 C.F.R. §2.208, as well as the substantiation questions (discussed more below). *See, e.g.*, EDF Br. 45 ("[Section] 2.208 does not include one of the criteria required for confidentiality by TSCA §14."). EPA must scrutinize confidentiality claims to determine whether the claimant truly has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering," and neither §2.208 nor any other provision of the regulations requires EPA to do so. EPA fails to respond to this aspect of EDF's challenge.

In its Brief, EPA never commits to reviewing confidentiality claims against this criterion. Instead, in a *post hoc* argument, EPA contends that as long as a person submits a statement asserting this criterion to support the claim, EPA will somehow scrutinize the merits of the confidentiality claim without considering whether it actually meets this substantive criterion. *See* EPA Br. 35-36. Under this interpretation, EPA transforms Congress's carefully crafted list of four criteria for confidentiality claims into a procedural formality with no substantive effect. *See*

*Pub. Citizen*, 332 F.3d at 671 (rejecting interpretation of provision that rendered it "little more than an empty gesture"). This interpretation undermines Congress's purpose in setting forth criteria for confidentiality claims and appears nowhere in the administrative record. This Court should reject it.

### B. EDF has standing to challenge the substantiation questions regarding reverse engineering.

EPA contends (Br. 34-35) that EDF lacks standing to challenge the substantiation questions regarding reverse engineering. EPA suggests that it is unlikely that a person would state that they have "a reasonable basis to believe that the information is not readily discoverable through reverse engineering," 15 U.S.C. §2613(c)(1)(B)(iv), but then also have answers to specific substantiation questions that are insufficient to sustain that broad claim. EPA Br. 33-35.

*First*, every legal practitioner knows that people often make statements that collapse under follow-up questions or scrutiny of the underlying facts. *See, e.g.*, *United States v. Green*, 670 F.2d 1148, 1154 (D.C. Cir. 1981) ("For two centuries judges and lawyers have regarded the opportunity of cross-examination as an essential safeguard of the accuracy and completeness of testimony."). Here, one of the proposed rule's substantiation questions asked: "Does this particular chemical substance leave the site of manufacture in any form, e.g., as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?" EPA-HQ-OPPT-2016-0426-0001 p.14 (JA:014). Another asked: "If

the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?" *Id.* Some persons will likely assert that their chemical is not readily discoverable through reverse engineering, but then have inadequate or unconvincing answers to these (and other) questions. The statute requires EPA to deny the confidentiality claim in such circumstances and publish the information. 15 U.S.C. §2613(g)(1)(A).

Indeed, if a person had no answer to these questions *and* had to answer them, then they would not assert a confidentiality claim at all. Then EPA would publish the underlying information. But under the final rule, where no questions addressing this criterion are asked, a person may well assert the confidentiality claim because EPA will not scrutinize the underlying substance of their assertion about reverse engineering. EPA has removed the incentives for persons not to make this assertion by indicating that EPA will not scrutinize the claims for compliance with this criterion. *See, e.g.*, *In re Idaho Conservation League*, 811 F.3d 502, 510 (D.C. Cir. 2016) (relying on incentives to find standing).

*Second*, EDF cited evidence that when EPA scrutinizes confidentiality claims, it often finds them invalid. EDF Br. 6-7, 29. If EPA scrutinized the reverse-engineering criterion for confidentiality claims, it would likely result in the

denial of some claims. Congress required the substantiation of most claims, 15 U.S.C. §2613(c)(3), so Congress believed it would affect the outcome.

*Third*, "[a] plaintiff who alleges a deprivation of a procedural protection to which he is entitled never has to prove that if he had received the procedure the substantive result would have been altered. All that is necessary is to show that the procedural step was connected to the substantive result." *Sugar Cane Growers Coop. of Fla. v. Veneman*, 289 F.3d 89, 94-95 (D.C. Cir. 2002). Here, EPA's failure to require any substantiation of one of the four criteria for confidentiality claims denies EDF (and the public generally) of a procedure (substantiation) designed to influence the outcome of EPA's confidentiality determinations. EDF has an interest in the outcomes of those determinations. EDF Br. 23-28. EPA "cannot defeat standing merely by asserting that it will come to the same conclusion once" it institutes the procedure required by Congress. *ADX Commc'ns of Pensacola v. FCC*, 794 F.3d 74, 82 (D.C. Cir. 2015).

### C. No one disputes that EPA failed to consider an important aspect of the problem.

With the final rule, EPA failed to consider whether or how to substantiate the reverse-engineering aspect of confidentiality claims. EPA's analysis is arbitrary and capricious because EPA has "entirely failed to consider an important aspect of the problem." *State Farm*, 463 U.S. at 43. EPA's redundancy argument (Br. 36) is irrational. All of the remaining substantiation questions somewhat

overlap with the *other* substantive criteria for confidentiality claims, as one would expect (the questions are designed to verify that the criteria supporting the claim are met). None of the remaining questions are redundant with the reverse-engineering criterion. Moreover, while EPA has discretion to shape the substantiation process, that discretion is bounded by the APA's requirement for reasoned decisionmaking. EPA has abused its discretion by acting arbitrarily and capriciously.

## III. EPA has systematically violated the procedural requirements of TSCA §14, and EPA has not incorporated those requirements into this rule.

EDF raised this issue during the rulemaking, EPA-HQ-OPPT-2016-0426-0064 p.17 (JA:110) (arguing that "EPA's rule needs to make clear that the section 14 requirements apply," including requirements about "the assertion, substantiation and review of CBI claims"), and in any event EPA has an obligation to follow the law.

### A. EPA has committed hundreds or thousands of violations of TSCA §§14(g)(1) and 26(j) over the last two years.

EPA does not dispute that under TSCA §14(g)(1), EPA must review certain confidentiality claims within 90 days of receipt, and under TSCA §26(j), EPA must publish the determinations it reaches on those confidentiality claims. 15 U.S.C. §§2613(g)(1), 2625(j). In the two years since the passage of the Lautenberg Act, EPA has not yet published a *single* determination, indicating that EPA has not

completed its review of a single confidentiality claim, despite the 90-day deadline applicable to many claims.

EPA has received many claims during that time and kept information confidential without determining whether confidentiality is warranted. For example, EPA received notices of commencement for certain chemicals with specific chemical identity claimed confidential shortly after the passage of the Lautenberg Act—*e.g.*, EPA received the notice for P-16-0250 on June 24, 2016. 81 Fed. Reg. 49,976, 49,981 (July 29, 2016). EPA had to make a determination on those claims within 90 days of receipt. 15 U.S.C. §2613(g)(1)(A), (g)(1)(C)(i). EPA should have published its first determination no later than September 22, 2016. EPA has not published its determination on that confidentiality claim, yet EPA is maintaining the confidentiality of that chemical (only the generic name appears on the Inventory). Between June 2016 and February 2018, EPA received over 200 notices of commencement with generic names (and thus confidentiality claims for specific chemical identity), *see, e.g.*, 81 Fed. Reg. at 49,981, yet EPA has not published a single determination on those claims, despite expiration of the 90-day deadline for review. EPA has also not yet published a single determination on any of the hundreds or thousands of other confidentiality claims that have been received over the past two years. EDF has repeatedly informed EPA about these ongoing violations. *See, e.g.*, EDF Comments on New Chemicals Program,

pp.25-26, *available at* https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0585-0071.

Given rampant violations of these statutory requirements, this Court cannot credit EPA's assurances (EPA Br. 14) that it will comply with these requirements in the future.

### B. EDF's concerns about violations are not speculative or non-imminent when EPA systematically commits these violations.

EDF has standing to challenge EPA's failure to incorporate the requirements of TSCA §§14 and 26(j) into the regulations. EPA's consistent violations of its duties under TSCA §§14(g)(1) and 26(j) provide an indisputable factual basis for EDF's concern that EPA will violate these duties going forward. EDF's concerns are not speculative or non-imminent; EPA commits these violations and injures EDF (and the public) almost every day.

EPA has also already committed these violations when acting pursuant to the challenged rule. The reporting period for manufacturers (including importers) ended on February 7, 2018. Under TSCA, EPA must review 25% of all non-chemical identity confidentiality claims made on reporting forms within 90 days of receipt. *See* 15 U.S.C. §2613(g)(1)(A), (g)(1)(C)(ii). When EPA makes a determination about those claims, EPA must publish the determination under TSCA §26(j)(1). *Id.* §2625(j)(1). The 90 days passed on May 8, 2018, but EPA

has not published a single determination as of the date of this Brief's filing, violating its duties under TSCA §§14(g)(1) and 26(j)(1).

Thus, unless EPA did not receive any confidentiality claims on those notices aside from claims for specific chemical identity (a highly unlikely possibility), EPA has already violated these statutory provisions. Meanwhile, if this Court orders EPA to incorporate these requirements into the regulation, then EPA will have to comply with the regulation and thus comply with these statutory provisions. *See, e.g.*, *Idaho Conservation League*, 811 F.3d at 512 (assuming for purposes of standing that EPA will comply with court orders, promulgate required regulations, and then comply with them).

Intervenors contend (Br. 27-28) that EDF lacks standing to challenge the failure to make or publish these determinations because a court may later review the determination through an appeal process. But TSCA §26(j)(1) requires that EPA "shall make available to *the public—all* notices, *determinations*, [and] *findings*," 15 U.S.C. §2625(j)(1) (emphases added), so EPA must publish these determinations, and the disclosure requirement does not await later steps by EPA. EDF has a right to information under the statutory language.

EDF also has prospective concerns. When a person submits a notice to change the status of a confidential chemical from "inactive" to "active," the person must assert and substantiate any confidentiality claim for the specific chemical

identity, and EPA must review and decide such a claim within 90 days. 15 U.S.C. §§2607(b)(5)(B), 2613(g)(1)(A). EPA must also publish EPA's determination. *Id.* §2625(j)(1). EDF has strong evidence that EPA will not meet those obligations. EPA has violated them in the past, and the regulations, as written, do not require EPA to take those actions.

Intervenors appear (Br. 28-29) to contend that this rulemaking does not govern prospective reporting of inactive to active status changes under TSCA §8(b)(5)(B). But this rulemaking codified this provision with the Notice of Activity Form B process. EPA-HQ-OPPT-2016-0426-0070 p.24 (JA:146) (40 C.F.R. §710.30(b)). Intervenors also suggest (Br. 28-29) that confidentiality claims for prospective reporting are reviewed under the five-year review plan, but that is wrong. The review plan governs solely retrospective reporting under TSCA §8(b)(4)(B). 15 U.S.C. §2607(b)(4)(C). Prospective reporting occurs under TSCA §8(b)(5). *Id.* §2607(b)(5).

**C. Following the regulations as written leads to statutory violations.**

EDF has asked this Court to vacate the regulation requiring that confidentiality claims be "treated and disclosed in accordance with 40 CFR part 2, subpart B." EPA-HQ-OPPT-2016-0426-0070 p.24 (JA:146) (40 C.F.R. §710.37(b)). This text does not require compliance with TSCA §14, and following subpart B will lead to violations of TSCA §14.

As EDF explained in its Opening Brief, "EPA's subpart B regulations only require EPA to review confidentiality claims in certain specified circumstances, 40 C.F.R. §2.204(a)," and they do not include deadlines for action. EDF Br. 49. These provisions of the rule violate TSCA because, under the statute, EPA has a proactive duty to review additional claims within a 90-day deadline and publish the determination. EPA needs to promulgate regulations that will lead to statutory compliance; *i.e.*, that require review of the subsets of claims identified in 15 U.S.C. §2613(g)(1)(C) within 90 days. And EPA's commitment to statutory compliance in the preamble does not fix the Code of Federal Regulations, which only requires review in the limited circumstances identified in 40 C.F.R. §2.204(a).

EPA also suggests (Br. 43) that there is no conflict between 40 C.F.R. §2.306(e) and TSCA because §2.306(e) provides a 30-day period to appeal confidentiality determinations, but in fact, TSCA sometimes provides only 15 or zero days to appeal. *See* 15 U.S.C. §2613(g)(2)(C).

In its Brief, EPA does not dispute that EPA must publish confidentiality determinations under TSCA §26(j)(1). 15 U.S.C. §2625(j)(1). But nothing in the regulations requires EPA to do so, and EPA has never done so. EPA's regulations are unlawful because EPA does not commit to complying with this statutory duty. EPA's sole articulated rationale (Br. 43-44) for failing to codify this duty is that the

duty does not require codification. But as EPA has systematically failed to comply with this duty, that rationale fails.

## IV. EPA's *post hoc* rationale for failing to address the unique identifier and other public information requirements is contrary to law and arbitrary and capricious.

EPA does not dispute that it failed to address the "unique identifier" requirement and several other "public information" requirements of TSCA §8(b)(7) when promulgating this rule. EPA Br. 44-47. Instead, EPA presents a *post hoc* rationale that the unique identifier issue is a separate matter. This rationale collapses upon scrutiny at several different points.

EPA now contends that it can postpone consideration of unique identifiers until after it has completed its rulemaking for the review of those confidentiality claims for specific chemical identity asserted during retrospective reporting and has approved claims under the review plan. EPA Br. 45. Nothing in the statute links unique identifiers to this review process. In fact, EPA must list unique identifiers for all confidential chemicals on the Inventory, whereas the review plan only governs review of the subset of confidentiality claims asserted during the retrospective reporting period. *Compare* 15 U.S.C. §2607(b)(7)(B), *with* 15 U.S.C. §2607(b)(4)(C).

TSCA §8(b)(7) states that the Inventory "*shall make available* to the public *** the unique identifier assigned under section 14, accession number, generic

name, and, if applicable, premanufacture notice case number for each chemical substance on the confidential portion of the [Inventory] *for which a claim of confidentiality was received*." 15 U.S.C. §2607(b)(7) (emphases added).

*First*, Congress made unique identifiers part of the Inventory, so it was arbitrary and capricious for EPA to refuse to consider how to implement this requirement when promulgating the rule governing the Inventory. TSCA §8(b)(7) imposes a duty on EPA to disclose information received through this rulemaking, so EPA must address this duty in promulgating this rule. *Id.* The plain language also requires that EPA place unique identifiers on the Inventory, and EPA cannot evade that duty.

*Second*, in TSCA §8(b)(7)(B), Congress directed EPA to provide unique identifiers for each chemical on the confidential portion of the list "for which a claim of confidentiality was received." *Id.* Thus, with respect to active chemicals already on the Inventory, EPA is supposed to list the unique identifier when a "claim of confidentiality was received"; this duty does not turn on approval of the confidentiality claim. Congress chose "receipt" as a trigger for disclosing the unique identifier under TSCA §8 specifically because the review and approval of claims under TSCA §8(b)(4)(C) could take years and the public needs the unique identifier so that they can link pieces of information about the chemical.

*Third*, assume for the sake of argument that EPA is correct that "TSCA §14, 15 U.S.C. §2613, provides for unique identifiers to be assigned once EPA 'approves' a confidentiality claim." EPA Br. 45. The Inventory must include numerous confidential chemicals where the claim for confidentiality must be reviewed within 90 days of EPA's receipt of a notice, not under the five-year review plan. Thus, EPA must include on the Inventory some confidential chemicals to which EPA should apply unique identifiers—under Respondents' own theory—with the very first publication of the updated Inventory.

For example, EPA must add to the Inventory new chemicals reported under the TSCA §5 new chemical program upon receiving a notice of commencement. 15 U.S.C. §2607(b)(1). EPA must review and decide any claim of confidentiality for specific chemical identity for such chemicals within 90 days of receipt. *Id.* §2613(g)(1)(A), (g)(1)(C)(i). Under EPA's own theory of TSCA §14(g)(4), EPA should assign a unique identifier for these chemicals within 90 days of receiving the notice of commencement (*i.e.*, within 90 days of placing the chemical on the Inventory). As explained *supra* at p.19, EPA receives numerous notices of commencement under the new chemicals program each month. *See, e.g.*, 81 Fed. Reg. 49,976, 49,981 (July 29, 2016). But EPA has not provided unique identifiers for these chemicals even when EPA allows the claimant to use a generic identity (hiding the specific identity). For example, EPA received the notice of

commencement for P-16-0250 on June 24, 2016, 81 Fed. Reg. at 49,981, and EPA continues to conceal its specific identity on the Inventory, but EPA has not provided a unique identifier on the Inventory. Under its own theory, EPA should have assigned a unique identifier for this chemical over a year ago.

Similarly, under TSCA §8(b)(5)(B), when a person submits a notice Form B to change the status of a confidential chemical from "inactive" to "active," the person must assert and substantiate any confidentiality claim for the specific chemical identity, and EPA must review and decide such a claim within 90 days. *Id.* §§2607(b)(5)(B), 2613(g)(1); *see also supra* at pp.21-22. Even if the assignment of the unique identifier awaits approval of the confidentiality claim, EPA must make that determination within 90 days of receipt of the Form B. EPA intends to update the Inventory approximately every six months in part to reflect these Form B notices. EPA-HQ-OPPT-2016-0426-0070 p.14 (JA:136). EPA will have to update the status of these chemicals no later than 6 months after completing the first updated Inventory, and under its own theory, EPA should assign unique identifiers to any such chemicals with approved confidentiality claims.

Thus, EPA's *post hoc* theory that the unique identifier issue can be postponed until after it conducts reviews under the five-year review plan is wrong. Even under EPA's theory that unique identifiers should be assigned after EPA's

review of the confidentiality claim, EPA must assign unique identifiers for some confidential chemicals on the Inventory before completing the rulemaking for and executing the review plan. A legally adequate Inventory rule would commit to meeting the public information requirements of TSCA §8(b)(7).

## V. Export-only chemicals are specifically "nonexempt" for purposes of TSCA §8.

TSCA §12(a)(1) states that "this Act (*other than section 8*) shall not apply to any chemical substance" if it is manufactured or processed solely for export and meets certain requirements. 15 U.S.C. §2611(a)(1) (emphasis added). Thus, the exemption provided by TSCA §12 expressly does *not* exempt export-only chemicals from TSCA §8, and it is TSCA §8 that includes the Inventory provisions at issue here. *See id.* §2607(b)(4). Congress decided that section 8 *shall* apply to such chemicals. For purposes of §8, chemicals manufactured or processed solely for export are "manufactured or processed for a nonexempt commercial purpose." *Id.* §2607(b)(4)(A)(i). Therefore, EPA should have required reporting for these chemicals. Respondents fail to address this statutory text; the actual language of TSCA §12(a)(1) does not appear in EPA's Brief.

Respondents attempt to make the issue complicated when it is clear. EPA pursues complicated (and largely *post hoc*) detours about a variety of other exemptions (EPA Br. 47-50), but the reasonableness of other exemptions is irrelevant. The statutory text expressly and clearly forecloses the export-only

exemption. *See United States Sugar Corp. v. EPA*, 830 F.3d 579, 650 (D.C. Cir. 2016) (agency may not assume a rationale for one exemption identically applies elsewhere).

Both Respondents focus on a red herring: that export-only chemicals are exempted from the new chemicals program under TSCA §5. EPA Br. 51; Intervenor Br. 33-35. The fact that TSCA §12 exempts export-only chemicals from the new chemicals program under TSCA §5 does not mean that they are exempt for purposes of reporting under TSCA §8. The statutory language distinguishes between these two situations, making export-only chemicals exempt from some TSCA provisions but *not* from §8.

While it is true that some export-only chemicals have never been added to the Inventory (because they were exempted from the TSCA §5 new chemicals program), those chemicals are already excluded from reporting under this rule because the statute limits the rule to "each chemical substance on the [Inventory]." 15 U.S.C. §2607(b)(4)(A)(i). EDF has not challenged EPA's definition of "reportable chemical substance" under 40 C.F.R. §710.23. That this definition excludes some export-only chemicals does not justify exempting *all* export-only chemicals, under EPA-HQ-OPPT-2016-0426-0070 p.22 (JA:144) (40 C.F.R. §710.27(a)(4)).

## CONCLUSION

For the above reasons, EDF requests that the Court grant the petition for review.

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## CERTIFICATE OF SERVICE

I hereby certify that on July 5, 2018, I electronically filed the foregoing brief with the Clerk of the Court for the United States Court of Appeals for the D.C. Circuit by using the appellate CM/ECF system.

All parties to the case have counsel who are registered CM/ECF users and service will be accomplished through the appellate CM/ECF system. Those counsel served by the appellate CM/ECF system include:

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