Environmental Defense Fund
Comments on
Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory
Docket ID: EPA-HQ-OPPT-2018-0320

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Environmental Defense Fund (EDF) appreciates the opportunity to provide comments on EPA's "Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory." 84 Fed. Reg. 16,833 (proposed Apr. 23, 2019). EPA must meet all of the requirements of TSCA §§ 8, 14, and 26, and EPA needs to modify the review plan regulation in numerous ways to achieve compliance with these sections.

The current review plan rule does not adequately address EPA's obligations to disclose specific chemical identities when claims are deficient. EPA must clearly commit to disclosing this information when confidentiality is withdrawn, not claimed, or not substantiated, or when EPA finds that confidentiality is not merited. In particular, failure to substantiate a claim should lead to disclosure of the specific chemical identity.

In the proposed rule, EPA erroneously suggests that specific chemical identity could be exempt from substantiation under TSCA § 14(c)(2), but for the chemicals subject to the review plan and that are on the Inventory, none is exempt from substantiation and EPA review as a matter of law. TSCA § 8 expressly requires substantiation for all confidentiality claims for specific chemical identity subject to this review plan, and it also requires EPA to review all such claims. EPA should eliminate the question suggesting that specific chemical identity could be exempt.

As a general matter, EPA needs to accept that TSCA § 14's express statutory requirements overrule any contrary regulations in EPA's general Freedom of Information Act (FOIA) regulations, and EPA's inclusion of cross-references to the FOIA regulations creates an inaccurate impression that these FOIA regulations take precedence over the statutory provisions of TSCA. EPA needs to eliminate some of these cross-references and to specify that TSCA § 14 takes precedence over any contradictory FOIA regulations.

In particular, EPA needs to codify the correct substantive standard for review of confidentiality claims. TSCA § 14(a) provides that information can only be withheld as confidential business information (CBI) under TSCA if it qualifies for withholding under FOIA Exemption 4 *and* if it meets the requirements of TSCA § 14(c). In *EDF v. EPA*, 922 F.3d 446, 453-55 (D.C. Cir.

2019), the D.C. Circuit clearly ruled that confidentiality claims must meet the substantive standard of TSCA § 14(c)(1)(B), and EPA needs to codify a standard that reflects that confidentiality claims must meet the criteria specified in TSCA § 14(c)(1)(B). The Court also made it clear that not being readily susceptible to reverse engineering is a substantive requirement for confidentiality claims, so EPA must incorporate this requirement into its substantive review of confidentiality claims. In addition, codifying the correct standard would help clarify that all substantiations and confidentiality claims will be held to the same substantive standard, so any person relying on a prior substantiations does so at the significant risk that the prior substantiation did not address all the TSCA § 14(c)(1)(B) factors.

EPA must also make numerous changes to its substantiation process. EPA cannot rely on the substantiation questions in 40 C.F.R. § 710.37(c), which were expressly rejected by the Court as arbitrary and capricious in *EDF v. EPA*, 922 F.3d at 453-55. EPA should develop a robust set of substantiation questions that actually provide EPA with the information it will need to review the confidentiality claims asserted through this process against a substantive standard that reflects the requirements for both FOIA Exemption 4 and TSCA § 14(c). In addition, there are inconsistencies between the substantiation questions in section 710.37(c) and those in another current EPA proposal to revise and amend the confidentiality provisions governing the Chemical Data Reporting (CDR) Rule. *See* 84 Fed. Reg. 17,692, 17,726 (proposed Apr. 25, 2019) (to be codified at 40 C.F.R. § 711.30). As a general rule, EPA should strive to make these rules coherent and consistent with each other. EDF argues for specific substantiation questions and modifications in section 7.A of these comments.

In addition, in the current proposed rule, EPA exempts from substantiation any person who completed the voluntary substantiation process in the Inventory notification rule. *See* 84 Fed. Reg. at 16,833 (proposed 40 C.F.R. § 710.43(b)(1)). But the D.C. Circuit has now ruled that the substantiation process was arbitrary and capricious for failing to make the necessary inquiries. *EDF v. EPA*, 922 F.3d at 454-55. As a practical matter, EPA has no choice but to require claimants to substantiate again and completely.

EPA also must modify the proposed rule to provide adequate, and legally required, public disclosure of the outcomes of this review process. Specifically, EPA must publish its determinations and the underlying findings on the confidentiality claims made through this process under TSCA § 26(j). EPA also must make changes to address confidentiality claims made within the substantiations that EPA receives; EPA's current proposal completely fails to address the most likely scenario where parts of a substantiation do not meet the standard for confidentiality, even if parts of it do. *See* 15 U.S.C. § 2613(b)(1).

EPA should also stagger the substantiation process to avoid relying on stale substantiations in the later years of this review process. On an annual basis, EPA could identify in the Federal Register approximately one-fifth of specific chemical identities subject to confidentiality claims under this rule, and EPA could require that all confidentiality claimants for that fifth substantiate

their claims or identify their prior substantiations within 90 days of publication of EPA's annual notice. Such an approach would ensure that EPA is not relying on overly dated substantiations when reviewing claims.

Because claimants are asserting claims for specific chemical identity, EPA must also require the structurally descriptive generic names required by TSCA § 14(c)(1)(C). Those generic names must meet the requirements of TSCA § 14(c)(1)(C), as well as EPA guidance, and many current generic names on the Inventory do not all meet those requirements. EPA should clarify that it will also be reviewing the generic names of these chemicals as part of its review of the confidentiality claims under the review plan. EPA should analyze the generic name carefully when reviewing the confidentiality claim for a specific chemical identity and should address the appropriateness of the generic name in any final approvals.

Finally, EPA should codify its obligation "to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure." 15 U.S.C. § 2613(g)(4)(A)(i).

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1. Legal Background: EPA must meet all of the requirements of TSCA §§ 8, 14, and 26.

A. Section 8 imposes numerous requirements on the CBI review plan.

Under TSCA § 8, "all" persons asserting confidentiality claims for specific chemical identity pursuant to that section must substantiate those claims as a matter of law, either in response to this review plan "at a time specified by the Administrator," or during a preceding five-year period. *See* 15 U.S.C. § 2607(b)(4)(D)(i). EPA must make determinations on "each" such confidentiality claim; when reviewing claims, EPA must "approve, approve in part and deny in part, or deny each claim." 15 U.S.C. § 2607(b)(4)(D)(ii)(I), (II).

In cases where EPA grants a claim, EPA then may only provide protection from disclosure of the information subject to the claim "for a period of 10 years" (subject to extension). *Id.* § 2607(b)(4)(D)(ii)(III). EPA must withdraw the protection if the claimant "withdraw[s] the claim, in which case [EPA] *shall* not protect the information from disclosure." *Id.* § 2607(b)(4)(D)(ii)(III)(aa) (emphasis added). In addition, if EPA "otherwise becomes aware that the information does not qualify for protection from disclosure, in which case [EPA] *shall* take the actions described in section 14(g)(2)." *Id.* § 2607(b)(4)(D)(ii)(III)(bb) (emphasis added).

EPA must complete the reviews of all claims "not later than 5 years" after February 19, 2019. *See* 15 U.S.C. § 2607(b)(4)(E)(i); *see also* EPA Releases First Major Update to Chemicals List in 40 Years, https://www.epa.gov/newsreleases/epa-releases-first-major-update-chemicals-list-40-years. EPA may extend the deadline for completion of the review "for not more than 2 additional years, after an adequate public justification, if the Administrator determines that the extension is necessary based on the number of claims needing review and the available resources." 15 U.S.C. § 2607(b)(4)(E)(ii)(I). "At the beginning of each year, the Administrator shall publish an annual goal for reviews and the number of reviews completed in the prior year." *Id.* § 2607(b)(4)(E)(ii)(II).

B. Confidentiality claims must be asserted, substantiated, and reviewed as required by TSCA § 14.

EPA may only allow confidentiality claims for specific chemical identity that meet all of the requirements of TSCA § 14 because TSCA § 8 incorporates the requirements of TSCA § 14 into the Inventory notification and CBI review plan processes. The Lautenberg Act requires that any claim for confidentiality made through the Inventory reset process is made "pursuant to section 14" and must "require the substantiation of those claims pursuant to section 14." 15 U.S.C. § 2607(b)(4)(B). The review plan must require substantiations "in accordance with section 14," 15 U.S.C. § 2607(b)(4)(D)(i), and EPA must "review each substantiation" "in accordance with section 14." *Id.* § 2607(b)(4)(D)(ii). Thus, each substantiation and review of a confidentiality claim pursuant to these notification and review processes must meet the requirements of section 14.

The Lautenberg Act substantially revised TSCA § 14, 15 U.S.C. § 2613, which governs the disclosure of information covered by FOIA Exemption 4. Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), Pub. L. No. 114-182, § 14, 130 Stat. 448, 481 (June 22, 2016). TSCA § 14 provides that, "[e]xcept as provided in this section, [EPA] shall not disclose information that is exempt from disclosure pursuant to [Exemption 4 of FOIA]—(1) that is reported to, or otherwise obtained by, [EPA] under [TSCA]; and (2) for which the requirements of subsection (c) are met." 15 U.S.C. § 2613(a). As a result, EPA can now only protect information from disclosure if each of two separate standards is met. First, to refuse to disclose information, EPA has to establish that information falls within FOIA Exemption 4. Exemption 4 provides that FOIA does not require disclosure of "matters that *** are trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). Second, EPA also has to determine that the information meets the requirements of TSCA § 14(c).

TSCA § 14(c) provides additional requirements for confidentiality, creating a three-step procedure for asserting and substantiating a claim. At the first step, a person must assert the claim and make a statement supporting the claim when the person submits the information. 15 U.S.C. § 2613(c)(1)(A).

An assertion of a claim *** shall include a statement that the person 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 person; and
> (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Id. § 2613(c)(1)(B). Any claim for confidentiality of specific chemical identity must be accompanied by this required statement.

The second procedural step is substantiation. While TSCA § 14(c)(2) exempts certain information from the substantiation requirements, claims for specific chemical identity are exempt from substantiation only in the limited circumstance defined in TSCA § 14(c)(2)(G), which applies "[p]rior to the date on which a chemical substance is first offered for commercial distribution." *Id.* § 2613(c)(2)(G). As explained more below, none of the chemical substances on the Inventory qualifies for the exemption because they have all been offered for commercial distribution at some point in the past. Thus, for all of these claims, "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim." *Id.* § 2613(c)(3). If there were any doubt, TSCA § 8 expressly requires that persons substantiate the

claims now or at some point in a preceding five-year period. *See id.* § 2607(b)(4)(D)(i), (ii). Thus, substantiation is required for every single claim for confidentiality for specific chemical identity asserted through this process.

At the third procedural step, EPA must review certain claims and make a decision on the claims. EPA must review "all" confidentiality claims for specific chemical identities (except for those subject to TSCA § 14(c)(2)(G)). 15 U.S.C. § 2613(g)(1)(C)(i). As noted above, TSCA § 8(b)(4)(D)(ii)(II) requires that EPA make a determination on each claim for protection of a specific chemical identity subject to this review process.

If EPA denies the claim, EPA must notify the claimant, who then has a short time period to file a lawsuit against EPA challenging disclosure. *Id.* § 2613(g)(2)(A), (D). EPA must disclose the information if the person does not file such an appeal.

C. Because claimants are asserting claims for specific chemical identity, EPA must also require the structurally descriptive generic names as required by TSCA § 14(c)(1)(C).

TSCA § 14(c)(1)(C) requires that claims for confidentiality for specific chemical identity must meet certain additional requirements. Structurally, Congress placed these requirements under TSCA § 14(c)(1) governing the "assertion of claims." 15 U.S.C. § 2613(c)(1)(C). Thus, these requirements must be met when the claim is asserted and by their plain terms apply to all confidentiality claims for specific chemical identity.

Specifically, when asserting the claim for confidentiality:

> [T]he claim shall include a structurally descriptive generic name for the chemical substance that the Administrator may disclose to the public, subject to the condition that such generic name shall—
> (i) be consistent with guidance developed by the Administrator under paragraph (4)(A); and
> (ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—
> > (I) that are claimed as confidential; and
> > (II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

15 U.S.C. § 2613(c)(1)(C). Thus, when asserting a claim for confidentiality for specific chemical identity, the claimant must propose a generic name that "describe[s] the chemical structure of the chemical substance as specifically as practicable," and the claimant may only seek nondisclosure of those features that "are claimed as confidential" and "the disclosure of which would be likely to cause substantial harm to the competitive position of the person." *Id.*

In addition, the generic name must be consistent with the Guidance EPA developed pursuant to TSCA § 14(c)(4)(A).

While EPA already has generic names for the chemicals on the confidential portion of the Inventory, those generic names do not all meet the requirements of TSCA § 14(c)(1)(C). EPA must review those generic names as part of this process, and where required, EPA must require revisions to the generic names to the meet the requirements of TSCA § 14(c)(1)(C).

D. EPA must assign a unique identifier for each chemical substance on the confidential portion of the Inventory.

TSCA § 14(g)(4) requires that EPA "shall develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term." 15 U.S.C. § 2613(g)(4)(A)(i). EPA must then "apply that identifier consistently to all information relevant to the applicable chemical substance." *Id.* § 2613(g)(4)(A)(ii).

EPA must comply with these duties with respect to each chemical substance where EPA approves a confidentiality claim through the review plan.

E. EPA must publish its determinations on the confidentiality claims made through this process under TSCA § 26(j).

TSCA § 26(j)(1) provides that: "Subject to section 14, [EPA] shall make available to the public all notices, *determinations*, *findings*, rules, consent agreements, and *orders* of the Administrator under this title." 15 U.S.C. § 2625(j)(1) (emphases added). TSCA § 14(g)(1) describes EPA's decisions about confidentiality claims as "determinations," and EPA must publish these determinations. Even if these decisions were not determinations, they would constitute "findings" and "orders" of the EPA under the plain meaning of those terms. In particular, EPA has to publish the "findings" underlying its determinations.

2. EPA's proposed rule correctly recognizes that the duration of protection for confidentiality claims is subject to the exceptions of TSCA §§ 8(b)(4)(D)(ii)(III) and 14(e).

Under TSCA § 8(b)(4)(D)(ii)(III), EPA shall protect for disclosure information subject to approved confidentiality claims "for a period of 10 years," subject to important exceptions. 15 U.S.C. § 2607(b)(4)(D)(ii)(III). EPA has correctly incorporated these exceptions into the proposed regulation at 40 C.F.R. § 710.55(b). Specifically, EPA has recognized that it should disclose information if the claimant notifies EPA that the person is withdrawing the claim *or* if EPA becomes aware that the information does not qualify for protection from disclosure, in which case EPA shall take the actions described in section 14(g)(2). *See* 15 U.S.C.

§§ 2607(b)(4)(D)(ii)(III), 2613(e)(1)(B)(ii). EPA appropriately codified these requirements for disclosure in its rule.

EPA correctly states that claims will be protected for 10 years from the date on which the claimant *first* asserts a claim of confidentiality after June 22, 2016. *See* 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.55(b)) (emphasis added). TSCA expressly states that confidentiality protection will only last for 10 years (subject to potential extensions under TSCA § 14(e)(2)). TSCA also explicitly states the "period of 10 years [runs] from the date on which the person asserts the claim with respect to the information submitted to [EPA]." 15 U.S.C. § 2613(e)(1)(B)(i). EPA has correctly recognized that this period should run from the date of the first filing of a request for confidentiality. *See* 84 Fed. Reg. at 16,831. Otherwise, EPA would be granting confidentiality protection for more than 10 years from the date on which the claim was asserted, in direct violation of the statutory text. Congress also created a detailed scheme for extensions of the confidentiality claims for an additional 10 years in TSCA § 14(e)(2), and EPA cannot allow persons to bypass this detailed scheme simply by submitting the confidentiality claim a second time.

One change EPA should make to its codification of these provisions is that EPA should remove the introductory clause: "Except as provided in 40 CFR part 2, subpart B." In the proposed rule at section 710.55(b), EPA is codifying statutory provisions, and the statutory requirements for disclosure overrule any contrary directives in EPA's general FOIA regulations. As a general matter, EPA needs to accept that TSCA § 14's express statutory requirements overrule any contrary regulations in EPA's general FOIA regulations, and the cross-references to the FOIA regulations create an inaccurate impression that these FOIA regulations take precedence over the statutory provisions of TSCA.

3. Failure to substantiate should lead to disclosure of the specific chemical identity.

In the proposed rule, EPA states that if no substantiation or submission identifying a prior substantiation are submitted when due, then EPA will consider the confidentiality claim to be deficient and EPA may make the information public without further notice. 84 Fed. Reg. at 16,829, 16,833 (to be codified at 40 C.F.R. § 710.49). EPA should change this "may" to a "shall"; when a claimant fails to substantiate a claim, EPA *must* disclose the information because the confidentiality claim cannot be upheld without substantiation.

The Lautenberg Act specifically requires that "*all* manufacturers or processors asserting claims" through this process "substantiate the claim, in accordance with section 14," unless they previously substantiated the claim during a preceding five-year period. 15 U.S.C. § 2607(b)(4)(D)(i). Substantiation is thus not optional, and any failure to substantiate the claims would render the confidentiality claim deficient; EPA would have no legal basis for failing to disclose the information if no substantiation is submitted or identified. Such deficient claims should be denied. In addition, EPA must "review *each* substantiation," *id.* § 2607(b)(4)(D)(ii)(I),

and EPA will only be able to fulfill this duty if persons have adequately identified the substantiation upon which they would like to rely.

Moreover, as discussed more below, the purpose of reviewing confidentiality claims is to ensure that EPA discloses those specific chemical identities which do not qualify for protection. If EPA fails to disclose specific chemical identities without valid confidentiality claims, EPA will be contravening Congress's entire purpose in including the review plan in the Lautenberg Act. EPA cannot adopt an interpretation of the Act which defeats Congress's purpose.

4. EPA must address what steps it will take upon denying a claim.

In the preamble to the proposed rule, EPA describes the initial steps it will take upon denying a claim. *See* 84 Fed. Reg. at 16,830. Specifically, EPA will notify the claimant and provide the claimant with 30 days to challenge a denial, as contemplated by TSCA § 14(g). *Id.* But EPA does not address what steps it will take: (1) if a claimant does not challenge the denial or (2) if the courts reject the claimant's challenge to the denial. Congress' clear intent in requiring a review of all confidentiality claims is for EPA to disclose information that does not merit protection. Once a claim has been denied (assuming no appeals or the exhaustion of appeals), EPA should commit to placing the specific chemical identity on the non-confidential portion of the Inventory and to disclosing that specific chemical identity to the public in the future. EPA must clearly commit to disclosing information when confidentiality is withdrawn, not claimed, or not substantiated, or when EPA finds that confidentiality is not merited.

5. EPA erroneously suggests that specific chemical identity could be exempt from substantiation under TSCA § 14(c)(2), but for chemicals on the Inventory, none are exempt from substantiation and review as a matter of law.

One of EPA's proposed substantiation questions asks if claimants believe the information is exempt from substantiation pursuant to TSCA § 14(c)(2). *See* 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.45) (stating that persons must answer questions appearing in 40 C.F.R. § 710.37(c)); 40 C.F.R. § 710.37(c)(1)(i) (asking whether information is exempt from substantiation under TSCA § 14(c)(2)). But for the claims for specific chemical identity submitted through the review plan, none can be exempt from substantiation as a matter of law.

First, in two places, TSCA § 8 expressly requires substantiation for all confidentiality claims for specific chemical identity subject to this review plan. In describing confidentiality claims made as part of the Inventory update process, TSCA § 8(b)(4)(B)(iii) expressly requires that EPA "shall *** require the substantiation of those claims pursuant to section 14." 15 U.S.C. § 2607(b)(4)(B)(iii). In describing the review plan, TSCA § 8(b)(4)(D) states that EPA "shall require, at a time specified by the Administrator, *all* manufacturers or processors asserting claims under subparagraph (B) to substantiate the claim, in accordance with section 14," unless they substantiated the claim in a preceding five-year period. 15 U.S.C. § 2607(b)(4)(D) (emphasis

added). As a matter of law, all confidentiality claims for specific chemical identity made through TSCA § 8(b) *must* be substantiated.

Second, by its plain terms, TSCA § 14(c)(2) does not exempt any claim for confidentiality for specific chemical identity for chemicals on the Inventory. TSCA § 14(c)(2)(G) exempts confidentiality claims for specific chemical identity "[p]rior to the date on which a chemical substance is first offered for commercial distribution." 15 U.S.C. § 2613(c)(2)(G). But chemicals on the Inventory have all been offered for commercial distribution; EPA adds chemicals to the Inventory upon receiving a notice of commencement of manufacture for nonexempt commercial purposes. 40 C.F.R. § 720.102(a). And TSCA § 14(g)(1)(C)(i) makes it clear that the only section 14(c)(2) exemption that could apply to specific chemical identity is section 14(c)(2)(G): TSCA § 14(g)(1)(C)(i) requires that EPA review "all" confidentiality claims for specific chemical identity *except* those subject to section 14(c)(2)(G).

Third, as explained above, EPA *must* review all the confidentiality claims for specific chemical identity made through this process. *See* 15 U.S.C. § 2607(b)(4)(D)(ii)(I), (II). EPA will need substantiations to perform those reviews, and indeed, EPA must "review each substantiation" "in accordance with section 14." *Id.* § 2607(b)(4)(D)(ii). EPA can only perform these reviews if it has the necessary substantiation. EPA cannot exempt any confidentiality claim for specific chemical identity made through this process from substantiation and review.

Therefore, EPA should not be asking submitters whether their confidentiality claims for specific chemical identity could be exempt under TSCA § 14(c)(2). As a matter of law, these claims are not exempt, they must be substantiated, and EPA must review them.

6. EPA must codify the correct substantive criteria for review of confidentiality claims.

EPA's current proposal is flawed because it codifies an incomplete and therefore wrong substantive standard for review of confidentiality claims. TSCA § 14(a) provides that information can only be withheld as confidential business information (CBI) under TSCA if it qualifies for withholding under FOIA Exemption 4 *and* if it meets the requirements of TSCA § 14(c). In its current proposal, EPA cross-references the requirements for confidentiality under FOIA Exemption 4, *see* 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.55(a)), but EPA completely fails to codify the requirements of TSCA § 14(c). For the reasons articulated below, EPA should separately codify the correct standard for confidentiality under TSCA in this rulemaking, and that standard should reflect the requirements for both FOIA Exemption 4 *and* TSCA § 14(c).

In particular, TSCA § 14(c)(1)(B) requires that confidentiality claims must be accompanied by certain factual assertions, and in reviewing the adequacy of these claims, EPA must ensure that those factual assertions have been adequately substantiated.

In the preamble to the proposed rule, EPA states that in reviewing claims:

> EPA would apply the substantive criteria for confidentiality determinations set forth in 40 CFR 2.208 and 2.306(g), which provide in relevant part that information is entitled to confidential treatment for the benefit of a particular business if: (a) The business has asserted a confidentiality claim which has not expired by its terms, nor been waived nor withdrawn; (b) the business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures; (c) the information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of need in a judicial or quasi-judicial proceeding); (d) no statute specifically requires disclosure of the information; and (e) the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position.

84 Fed. Reg. at 16,830; *see also* 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.55(a)). EPA must ensure that confidentiality claims meet these criteria to comply with TSCA's requirement that information will only be confidential if it meets the requirements for confidentiality under Exemption 4 of FOIA, as that standard existed at the time of the Lautenberg Act's enactment. *See* 15 U.S.C. § 2613(a). But TSCA imposes additional requirements for a claim of confidentiality, and EPA must update its substantive standard to reflect those additional factors.

First, information may only be confidential under TSCA § 14(c)(1)(B) if a person has correctly "determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law." 15 U.S.C. § 2613(c)(1)(B)(ii). EPA's current substantive standard does not fully capture this requirement because it allows confidentiality as long as "no statute specifically requires disclosure of the information." But TSCA is more demanding than that standard, requiring that EPA disclose the information if it must "be disclosed *or* otherwise made available to the public under *any other Federal law*." *Id.* (emphases added). Federal law encompasses federal regulations and rules, as well as federal statutes, and the TSCA standard asks whether the federal law requires disclosure *or* otherwise requires that the information be made available to the public; assuming that Congress does not enact meaningless words, this extra clause clearly intends to sweep more broadly than disclosure standing alone. Thus, if a federal *regulation* or other legal requirement mandates that information be disclosed or otherwise be made available to the public, EPA must also disclose the information under TSCA. EPA's current substantive standard does not reflect this broader requirement for confidentiality.

Second, information may only be confidential under TSCA § 14(c)(1)(B) if a person has "a reasonable basis to believe that the information is not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c)(1)(B)(iv). EPA's current substantive standard completely fails to capture this requirement for confidentiality. EPA has conceded in Court that information must not be readily discoverable through reverse engineering to be confidential under TSCA. *See EDF v. EPA*, 922 F.3d 446, 454-55 (D.C. Cir. 2019) ("But it makes no sense to treat as confidential the chemical identity of a substance that can readily be discovered through reverse engineering—as the EPA itself agrees. Oral Argument Tr. 24:48-24:59 ('[D]oes the EPA agree that if something is readily reversibly engineered [then] it doesn't qualify for confidential treatment?' [Agency counsel]: 'Yes.')."). That concession flowed from the clear requirement in TSCA § 14(c)(1)(B), and the Court made it clear that not being susceptible to reverse engineering is a substantive requirement for confidentiality claims, so EPA must incorporate this requirement into its substantive review of confidentiality claims. Lest there be any doubt, the D.C. Circuit described the inquiry into a "chemical identity's susceptibility to reverse engineering" as "a statutorily required criterion." *Id.* at *13.

Third, information may only be confidential under TSCA § 14(c)(1)(B) if a person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." 15 U.S.C. § 2613(c)(1)(B)(iii). EPA correctly identifies this required criterion in the preamble to the rule, but EPA should not rely on a cross-reference to the general FOIA regulations to codify this requirement for two reasons. On June 24, 2019, the Supreme Court issued a decision in *Food Marketing Institute (FMI) v. Argus Leader*, and the Court adopted a new interpretation of Exemption 4 of FOIA; the Court ruled that a showing of likely substantial harm to the competitive position is not required for confidentiality under FOIA Exemption 4. *Food Mktg. Inst. v. Argus Leader Media*, 2019 U.S. LEXIS 4200 (2019). Thus, *FMI* likely has significant implications for EPA's general FOIA regulations. But crucially, it has *no effect* on TSCA's requirements that information can only be claimed confidential if a person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." 15 U.S.C. § 2613(c)(1)(B)(iii). The Court relied on a textual, plain language approach to statutory interpretation of FOIA that here counsels in favor of being clear about the applicability of TSCA's requirement that persons make a showing that they have "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." 15 U.S.C. § 2613(c)(1)(B)(iii). EPA should codify the TSCA requirements in this specific rulemaking, rather than rely on a cross-reference in the preamble which may become inaccurate in the near future.

In addition, the substantive standard in the general FOIA regulations at 40 C.F.R. § 2.208 does not always require a person to meet TSCA's requirement that a person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." 15 U.S.C. § 2613(c)(1)(B)(iii). Specifically, 40 C.F.R. § 2.208(e) provides that a person "*either*" must show "that disclosure of the information is likely to cause

substantial harm to the business's competitive position *or* [that] [t]he information is voluntarily submitted information (see § 2.201(i)), and its disclosure would be likely to impair the Government's ability to obtain necessary information in the future." 40 C.F.R. § 2.208(e) (emphases added). Therefore, a person can obtain confidentiality under the general FOIA regulations without always showing that disclosure is likely to cause substantial harm to a claimant's competitive position, but TSCA includes no similar disjunctive exception to this requirement. Information can *only* be confidential under TSCA upon a showing that a person has "a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person." 15 U.S.C. § 2613(c)(1)(B)(iii). Thus, EPA cannot rely on a cross-reference to § 2.208 because it does not codify TSCA's substantive standard.

Thus, EPA must codify the substantive standard for review of confidentiality claims under the review plan, and EPA must ensure that the substantive standard is as demanding as required by TSCA § 14(c)(1)(B), *as well as* meeting the general requirements for confidentiality under Exemption 4 of FOIA.

7. EPA must modify its substantiation approach to comply with TSCA § 14 and with the Court of Appeals' remand in *EDF v. EPA*.

EPA's approach to substantiation must be modified to comply with TSCA § 14 and the D.C. Circuit's recent decision in *EDF v. EPA*, 922 F.3d 446, 454-55 (D.C. Cir. 2019). In *EDF v. EPA*, EDF "challenge[d] the EPA's failure to require companies to 'substantiate' that a chemical identity they wish to keep confidential is not 'readily discoverable through reverse engineering.' See 15 U.S.C. § 2613(c)(1)(B)(iv), (c)(3)." *EDF v. EPA*, 922 F.3d at 453. The Court agreed that the statute "specifically requires the company to 'substantiate' its confidentiality claim," including the required elements of the claim, such as that the chemical substance be not readily discoverable through reverse engineering. *Id.* at 453-54. The Court found that EPA's substantiation questions entirely failed to inquire into this factor. "[The] omission of any inquiry into a chemical identity's susceptibility to reverse engineering effectively excised a statutorily required criterion from the substantiation process. See 15 U.S.C. § 2613(c)(1)(B)(iv), (c)(3)." *Id.* at 454. "The Inventory Rule is arbitrary and capricious to the extent that it omits any substantiation requirement pertaining to reverse engineering." *Id.*

A. EPA cannot rely on the substantiation questions in 40 C.F.R. § 710.37(c).

EPA should develop a robust set of substantiation questions that actually provide EPA with the information it will need to review the confidentiality claims asserted through this process against a substantive standard that reflects the requirements for both FOIA Exemption 4 *and* TSCA § 14(c). While the questions EPA currently has codified at 40 C.F.R. § 710.37(c) should provide some of the information that EPA needs (with the exception of section 710.37(c)(1)(i), as explained in section 5 above), these questions will not be adequate to ensure that EPA has all the information it needs to review the confidentiality claims reviewed through this process.

In addition, there are inconsistencies between the substantiation questions in section 710.37(c) and those in another current EPA proposal to revise and amend the confidentiality provisions governing the Chemical Data Reporting (CDR) Rule. *See* 84 Fed. Reg. at 17,726 (to be codified at 40 C.F.R. § 711.30). For the most part, these inconsistencies make no sense because EPA is implementing the same provisions of TSCA § 14 in both rules. Both proposals fail to obtain some of the information that would be obtained with EPA's original substantiation questions which governed the CDR previously. *See* 40 C.F.R. § 711.30(b)(1). Those original substantiation questions need some additions in light of TSCA's more demanding standard for confidentiality after the passage of the Lautenberg Act. *See* 15 U.S.C. § 2613(c)(1)(B). However, EPA has no rational basis for seeking *less* information and imposing a *less* stringent standard for confidentiality claims after the Lautenberg Act; the Lautenberg Act added requirements for confidentiality claims, and it did not in any way diminish the requirements for confidentiality claims. Thus, EPA should generally view its duties as requiring confidentiality claims to meet a *higher* standard than they were held to under TSCA prior to the enactment of Lautenberg. Thus, while they need some updating in light of the Lautenberg Act, the existing provisions of section 711.30(b)(1) should be seen as a floor for substantiation questions.

To comply with TSCA § 14 and to ensure consistency, EPA should update its substantiation questions in the current proposal in the following ways:

First, as a general matter, EPA should clarify that persons need to submit "*detailed* written answers to" the substantiation questions. *See* 40 C.F.R. § 711.30(b)(1) (emphasis added). EPA has historically made this clear, *id.*, and EPA proposes to include this language in the proposed amendments to the CDR Rule, *see* 84 Fed. Reg. at 17,726. EPA will need detailed written answers to questions; simple "yes," and "no" responses would completely fail to "substantiate" the elements of the confidentiality claim. In addition, EPA should clarify that in reviewing claims it cannot rely on speculation and guesswork. EPA cannot rationally assume that a confidentiality claim meets the statutory requirements without adequate substantiation of the specific elements of the confidentiality claims; without sufficient information to support each specific factor, it would be arbitrary and capricious for EPA to simply assume the confidentiality claim meets the required factors.

Second, to address one of the new requirements of the Lautenberg Act, EPA must add questions addressing the statutory requirement that the information be "not readily discoverable through reverse engineering." 15 U.S.C. § 2613(c)(1)(B)(iv). EPA must also make this change to comply with the mandate in *EDF v. EPA*. In its current substantiation questions for the CDR Rule, EPA asks the following two questions which are reasonable first steps in ascertaining whether there is a reasonable basis to believe a chemical substance is or is not readily discoverable through reverse engineering:

- Does this particular chemical substance leave the site of manufacture (including import) in any form, e.g., as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?
- 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?

40 C.F.R. § 711.30(b)(1)(vii), (ix).[1] These questions would disclose some, but not all, of the information that EPA needs to determine whether a specific chemical identity is readily discoverable through reverse engineering. EPA needs to include these questions among the substantiation questions specified in the final review plan rule. But EPA should supplement the second question with a follow-up question to clarify the basis for any negative answer and to directly address whether existing technologies make it possible for the specific identity of the chemical substance to be readily discoverable. Multiple commercial entities widely advertise that they offer "reverse engineering" services.[2] These services state that they use multiple techniques to identify chemical substances, including, but not limited to, Gas Chromatography/Mass Spectroscopy (GC/MS), Liquid Chromatograph/ Mass Spectroscopy (LC/MS), Ion Chromatography (IC), and Fourier Transform Infrared Spectroscopy (FTIR).[3] EPA's substantiation questions must directly address whether these available techniques would be likely to be able to readily determine the specific identity of a chemical substance. For instance, EPA could ask: "Would existing technologies permit a competitor to reverse engineer the chemical identity of the substance? If not, please explain why not?" Without asking a question directly addressing the availability of these technologies, EPA will not be able to adequately determine whether the information can be readily discoverable through reverse engineering. EPA needs to add this substantive follow-up question because otherwise claimants could simply answer the question "no" with no explanation, which would give EPA inadequate information to assess whether there is a reasonable basis to believe the chemical substance is susceptible to reverse engineering.

Third, EPA must add a substantiation question to determine whether the "information is required to be disclosed or otherwise made available to the public under any other Federal law." 15 U.S.C. § 2613(c)(1)(B)(ii). Information only qualifies as confidential if a person has correctly "determined that the information is not required to be disclosed or otherwise made available to

[1] EPA also proposes to ask these questions in the proposed rule amending the CDR. *See* 84 Fed. Reg. at 17,726.

[2] A Google search for reverse engineering services, or "deformulation" services, identifies numerous analytical laboratories offering reverse engineering services. *See* Google Search for "deformulation service," https://www.google.com/search?q=deformulation+services&cad=h (last visited June 18, 2019).

[3] Avomeen Analytical Services, Product Deformulation Service, https://www.avomeen.com/scientific-applications/product-deformulation-service/ (last visited June 18, 2019); EAG Laboratories, Deformulation, https://www.eag.com/services/materials/deformulation/ (last visited June 18, 2019).

the public under any other Federal law." 15 U.S.C. § 2613(c)(1)(B)(ii); *see also* 15 U.S.C. § 2613(d)(8) (requiring disclosure "if the information is required to be made public under any other provision of Federal law."). Currently, none of EPA's substantiation questions asks this straightforward question, but EPA could easily add a substantiation question to inquire into this statutorily-required factor. EPA should ask: "Is this information ever required to be disclosed or otherwise made available to the public under any other Federal law?" Among other things, many members of the regulated community may be aware of federal disclosure requirements implemented by other agencies of which EPA may not be fully aware.

Fourth, EPA should ask further questions about the likelihood of substantial harm to competitive position, as it does in its current CDR Rule. Currently, EPA asks: "Will disclosure of the information likely result in substantial harm to your business's competitive position? If you answered yes, describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public." 40 C.F.R. § 710.37(c)(1)(ii). EPA should supplement this question with necessary follow-ups that are also in its current CDR Rule: "How could a competitor use such information? *** What is the causal relationship between the disclosure and the harmful effects?" 40 C.F.R. § 711.30(b)(1)(i). These additional questions will help elucidate whether and how substantial competitive harm would occur from disclosure. Without answers to these questions, a company's explanation of why and how disclosure would likely result in substantial harm may well lack the detail necessary for EPA to sufficiently evaluate the company's claim. For instance, EPA often receives substantiations in the new chemicals program that only loosely describe the alleged causal relationship between disclosure and competitive harm.[4] EPA should retain these questions in the final rule.

Fifth, EPA should ask questions designed to determine whether the information is truly confidential and meets the substantive requirement under FOIA that the "the information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of need in a judicial or quasi-judicial proceeding)." 40 C.F.R. § 2.208(c); *see also* 84 Fed. Reg. at 16,830. Thus, EPA should continue to ask the core question getting at this information: "Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential." 40 C.F.R. § 710.37(c)(2). In the current CDR Rule, EPA asks a straightforward question that also enquires into whether *competitors* could have discovered the information, as opposed to just the public at large: "Has the identity of the chemical substance

[4] *See, e.g.*, Substantiation in Public File for P-18-0021 at p. 6 (obtained by EDF from Docket Center) ("Disclosing the information stated above would be harmful to our competitive position. It *may provide* a useful insight into the direction of our research activities. If this information is known to the competitors, they *may replicate* our product without investing into research and development, and offer it at a lower price.") (emphases added).

been kept confidential to the extent that your competitors do not know it is being manufactured or imported for a commercial purpose by anyone?" 40 C.F.R. § 711.30(b)(1)(iv). This question is important for several reasons. Competitors often have access to numerous pieces of information that would allow them to determine that a chemical substance is being manufactured or imported, beyond the public's general ability to know such information about the chemical substance. To the extent competitors know about a chemical substance's existence in commerce, it loses its confidentiality *even if* the general public would not be aware of this information. In addition, this issue gets at the key question for purposes of evaluating claims for specific chemical identity: if competitors can determine that the substance is being manufactured "by anyone," then the identity should be disclosed even if a company could establish that it is the company's connection to a specific chemical identity that is information meriting confidential protection. In the latter circumstance, the correct approach is to disclose the specific chemical identity on the Inventory and to conceal the specific company name (assuming all other elements required for confidentiality are met). In any event, EPA correctly asked this question for many years, and as explained above, the Lautenberg Act made the standard for confidentiality *more* demanding, rather than less. EPA should ask this straightforward question here.

On this same point, EPA proposes to ask: "Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential." 40 C.F.R. § 710.37(c)(1)(iv). This question is good, though the presumption should generally be that an answer of "yes" to the initial question means that the information does not meet the requirements for confidentiality. This question should be amended by adding "patents or patent applications" to the list of public documents that can reveal a specific chemical identity. EPA's current CDR Rule identifies patents as generally requiring disclosure of chemical identity, 40 C.F.R. § 711.30(b)(1)(iii), and if a specific chemical identity has been patented, it therefore has been disclosed and cannot be confidential under TSCA. "[T]he ultimate goal of the patent system is to bring new designs and technologies into the public domain through disclosure." *Bonito Boats v. Thunder Craft Boats*, 489 U.S. 141, 151 (1989). While EPA's proposed question in principle should require claimants to identify patents and patent applications, EPA should add it to the list of examples to avoid any potential omissions or inaccurate reporting by claimants.

Similarly, EPA's current CDR Rule asks whether the information has been disclosed in "[s]tate, local, or Federal agency public files" when listing the public documents that claimed confidential information may appear in. EPA should add this list to its final question about whether the information appears in any public documents to make clear that EPA needs to know whether the information has been made public through disclosure to another governmental entity.

Thus, the final question should be: "Does the information appear in any public documents, including (but not limited to) safety data sheets; patents or patent applications; advertising or promotional material; professional or trade publication; state, local, or Federal agency files; or

any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential." 40 C.F.R. § 710.37(c)(1)(iv).

B. Because EPA cannot rely on the substantiation questions in 40 C.F.R. § 710.37(c), EPA cannot rely on the prior substantiations made pursuant to the process set forth in § 710.37(a)(1).

In the current proposed rule, EPA exempts from substantiation any person who completed the voluntary substantiation process in the Inventory notification rule. *See* 84 Fed. Reg. at 16,833 (proposed 40 C.F.R. § 710.43(b)(1)). But the D.C. Circuit has now ruled that the substantiation process was arbitrary and capricious for failing to make the necessary inquiries. *EDF v. EPA*, 922 F.3d 446, 454 (D.C. Cir. 2019). As a practical matter, EPA has no choice but to require claimants to substantiate again and completely. Even industry sources have recognized that a Court decision in EDF's favor on this issue would require claimants to re-substantiate or supplement their substantiations. *See* TSCA 30/30, https://www.khlaw.com/TSCA-3030-April-17-2019 (at 22 minutes and 16 seconds).

If EPA tried to allow claimants to rely on their prior substantiations, it would have to be with the crucial caveat that EPA failed to inquire into a statutorily mandated factor: reverse engineering. Because EPA must "review each substantiation" "in accordance with section 14," EPA must inquire into all the requirements of TSCA § 14, including whether there is a reasonable basis to believe the specific chemical identity is "not readily discoverable through reverse engineering." 15 U.S.C. §§ 2607(b)(4)(D)(ii), 2613(c)(1)(B)(iv). Persons relying on their old substantiation may have failed to provide any evidence or explanation as to this necessary factor. TSCA squarely places the burden of substantiating confidentiality claims on the claimant, *id.* § 2607(b)(4)(D)(i), and EPA would have to deny any confidentiality claim that fails to prove all the elements required for a confidentiality claim. So while EPA could allow claimants to rely on their old substantiations, the claimants would do so at the risk that EPA would deny their confidentiality claims for having failed to sufficiently substantiate the confidentiality claim.

Moreover, EPA's determinations on confidentiality will be judicially reviewable. Persons may reasonably submit a Freedom of Information Act (FOIA) request for the records containing the specific chemical identity. EPA must then defend any decision to withhold those records, and the burden will be on EPA to justify the withholding. *See* 5 U.S.C. § 552(a)(4)(B) ("[T]he burden is on the agency to sustain its action."); *United States DOJ v. Landano*, 508 U.S. 165, 171 (1993) ("The Government bears the burden of establishing that the exemption applies."). If EPA has no information justifying its conclusion that there is a reasonable basis to believe the specific chemical identity is "not readily discoverable through reverse engineering," 15 U.S.C. § 2613(c)(1)(B)(iv), then EPA will be unable to meet its burden and the courts will correctly order disclosure of the specific chemical identities.

Given these realities, EPA should not exempt the substantiations submitted through the voluntary substantiation process set forth in section 710.37(a)(1). EPA should require claimants to substantiate again, answering questions that actually provide the information EPA needs to make the necessary determinations under TSCA § 14.

C. EPA should clarify that all substantiations and confidentiality claims will be held to the same substantive standard, so persons relying on prior substantiations do so at the significant risk that the prior substantiation did not address all the TSCA § 14(c)(1)(B) factors.

TSCA contemplates that EPA may allow claimants to rely on substantiations submitted "during the 5-year period ending on the last day of the of the time period specified by the Administrator." 15 U.S.C. § 2607(b)(4)(D)(i). Thus, EPA can reasonably exempt persons from substantiating if they identify the prior substantiation as codified at proposed 40 C.F.R. § 710.43(b)(2). However, TSCA also clearly requires that *all* substantiations will be reviewed "in accordance with section 14." 15 U.S.C. § 2607(b)(4)(D)(ii). Thus, EPA must hold all confidentiality claims and their substantiations to the substantive standard codified in TSCA § 14, including TSCA § 14(c)(1)(B).

As explained above, TSCA § 14(c)(1)(B) includes four factors that every confidentiality claim must meet, including that the claimant 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 person; and
> (iv) a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

15 U.S.C. § 2613(c)(1)(B). In reviewing each confidentiality claim, EPA must review whether each of these statements has been adequately substantiated. Even if claimants choose to rely on older substantiations, they still must meet this substantive standard. As noted above, EPA should make this clear by codifying the correct substantive standard in the Review Plan Rule, and in the preamble, EPA should clarify that this standard will apply to older substantiations as well. Then claimants would be able to determine for themselves whether their prior substantiation adequately addressed all of TSCA's requirements.

As noted above, TSCA places the burden for substantiation on the claimant, so any failure to address a statutory factor should result in denial of the confidentiality claim. EPA cannot engage in speculation or conjecture to establish that a particular confidentiality claim meets the requirements of TSCA § 14.

8. EPA must ensure adequate public disclosure of this review process.

A. EPA must publish its determinations on the confidentiality claims made through this process under TSCA § 26(j).

EPA must commit to publishing its determinations on confidentiality claims. TSCA § 26(j)(1) provides that: "Subject to section 14, [EPA] shall make available to the public all notices, *determinations*, *findings*, rules, consent agreements, and *orders* of the Administrator under this title." 15 U.S.C. § 2625(j)(1) (emphases added). TSCA § 14(g)(1) describes EPA's decisions about confidentiality claims as "determinations," and EPA must publish these determinations. Even if these decisions were not determinations, they would constitute "findings" and "orders" of the EPA under the plain meaning of those terms. In addition, EPA has to publish the "findings" underlying its determinations.

In litigating *EDF v. EPA*, EDF argued that EPA had to publish its determinations on confidentiality claims. EPA *never* disputed that it had to publish such determinations; in fact, EPA expressly assured the Court that it would comply with this requirement. *See* Response Br. at pp.43-44. EPA stated that it did not have to codify this requirement because it was binding on its own terms. *See id.* While it is certainly true that EPA is bound to follow TSCA § 26(j) regardless of whether it separately codifies these requirements, EPA should still address this obligation in this rulemaking. EPA will need to implement this requirement in processing confidentiality claims through the review plan, and EPA should clarify how it intends to implement this provision. Moreover, EDF is now raising this issue in its public comments, and the issue merits a substantive response from EPA about whether and how it plans to implement this duty under the Act.

EPA has also previously adopted an interpretation of "determination" that statutorily required that "determination[s]" must be "explicit, written finding[s]." *Navistar, Inc. v. Jackson*, 840 F. Supp. 2d 357, 363 (D.D.C. 2012). While EPA was interpreting a different statute, the same basic reasoning applies here. Under the plain language of the word "determination," one expects an explicit, written finding on the question presented—here the legitimacy of the confidentiality claim. Moreover, TSCA § 26(j) expressly sweeps broadly to require EPA to disclose all aspects of its decision processes, requiring that EPA also disclose "findings." 15 U.S.C. § 2625(j)(1). In analyzing confidentiality claims, EPA will have to make "findings" on each aspect of the confidentiality claim. Those "findings" must be disclosed.

Moreover, EPA needs to issue its findings and determinations so that the public and regulated community can assess whether and how EPA is reviewing confidentiality claims. Such disclosure would be appropriate policy even if not statutorily required.

B. EPA must address the need for confidentiality claims made within the substantiations.

As currently drafted, the review plan only addresses how EPA will process confidentiality claims for specific chemical identity. But claimants will be submitting often-extensive substantiation documents that may include information of interest to the public or competitors. Claimants will likely want to make confidentiality claims for some of the information provided in the substantiation, but those should be allowed only to the extent warranted under TSCA. Currently, EPA's proposed review plan rule allows claimants to make a claim for the substantiation as a whole, but it completely fails to address the most likely scenario where parts of a substantiation do not meet the standard for confidentiality, even if parts of it do. *See* 15 U.S.C. § 2613(b)(1) (recognizing that confidential and non-confidential information can be mixed together and that only the confidential portions retain their confidentiality). Notably, EPA's current proposal for the CDR correctly recognizes that only portions of a substantiation are likely to merit confidentiality and the proposal correctly requires that persons identify which portions of the substantiation specifically merit confidential treatment. *See* 84 Fed. Reg. at 17,727 (to be codified at 40 C.F.R. § 711.30(g)).

EPA also has failed to consider how it will address any FOIA request made for these records. EPA should assume that members of the public may request these substantiation documents through the FOIA process. To assist EPA with processing any future FOIA requests made for these documents, EPA should add a more specific mechanism for claimants who wish to make confidentiality claims for any of the information in their substantiations. Thus, EPA should:

- Require that claimants specifically identify those portions of the substantiation that they claim are confidential, as in the Proposed CDR Rule at 40 C.F.R. § 711.30(g).
- Require that claimants submit "sanitized" versions of their substantiations which redact the specific information that is claimed confidential.
- Require that claimants submit their substantiations for these additional claims at the time of submission, as required by 15 U.S.C. § 2613(c)(3).
- Describe how EPA will review a representative subset of these claims, as required by TSCA § 2613(g)(1)(A), (C).

9. EPA should stagger the substantiation process to avoid relying on stale substantiations in the later years of this review process.

Under the current proposal, *all* manufacturers and processors must substantiate at the same time: within 90 days of the effective date of the final rule. *See* 84 Fed. Reg. at 16,833 (to be codified at 40 C.F.R. § 710.47(a), (b)). This approach means that EPA will be relying on years-old, likely stale substantiations late in the review process. For example, in the last year of the five-year review process, EPA may be relying on substantiations submitted almost five years previously, or even 10 years since claimants may have identified almost five-year old substantiations at the

outset of this process. If EPA extends this process to seven years, as provided for in TSCA § 8(b)(4)(E)(ii)(I), then it would be relying on substantiations that are almost seven years old (12 years old for claimants relying on prior substantiations). Any such substantiation will likely be very stale, including inaccurate information and, perhaps more importantly, excluding all relevant information that arose during the intervening period.

Each of the factors that EPA must consider in analyzing these claims is subject to change with time. *See, e.g.,* 15 U.S.C. § 2613(c)(1)(B). For example, whether disclosure would affect a person's competitive position may have a completely different answer after five or ten years have passed. Moreover, something initially kept secret may have become publicly known due to changes in circumstances.

Based on the Inventory notification process, EPA now knows the universe of chemicals subject to this rule. On an annual basis, EPA could identify in the Federal Register approximately one-fifth of specific chemical identities subject to confidentiality claims under this rule, and EPA could require that all confidentiality claimants for that fifth substantiate their claims or identify their prior substantiations within 90 days of publication of EPA's annual notice. EPA could then review those claims over the ensuing year of the review plan, and repeat this process until all claims have been timely substantiated and reviewed. TSCA provides EPA with the authority to identify the timing of submission of substantiations, and does not require all substantiations to be submitted by a single deadline. *See* 15 U.S.C. § 2607(b)(4)(D)(i) (allowing EPA to identify substantiation period). If EPA took this approach, then it would never be relying on a stale substantiation. While in cases where a claimant is relying on a prior substantiation, that substantiation may still be somewhat stale (up to five years old), it would be a vast improvement over relying on substantiations as old as ten to twelve years.

The statute suggests that Congress had such an approach in mind by requiring that EPA publish its annual goal of reviews at the beginning of each year. *See* 15 U.S.C. § 2607(E)(ii)(II). The annual publication requirements are completely consistent with EPA identifying goals for review with each year and requiring substantiations be submitted at the outset of each year of the review plan.

10. Because claimants are asserting claims for specific chemical identity, EPA must also require the structurally descriptive generic names required by TSCA § 14(c)(1)(C).

TSCA § 14(c)(1)(C) requires that every time someone "assert[s]" a claim for confidentiality for specific chemical identity, "the claim shall include a structurally descriptive generic name for the chemical substance that [EPA] may disclose to the public, subject to" certain conditions. 15 U.S.C. § 2613(c)(1)(C). EPA itself has recognized that claimants are "asserting" claims through the Inventory notification and review plan processes. *See* 84 Fed. Reg. at 16,831 (quoting 15 U.S.C. § 2607(b)(4)(D)(i)); *see also* 15 U.S.C. § 2607(b)(4)(C). The statute itself clarifies that "all manufacturers or processors [are] asserting claims" through the Inventory notification

process. 15 U.S.C. § 2607(b)(4)(D)(i). Therefore, the claims must include the generic name required by TSCA § 14(c)(1)(C). 15 U.S.C. § 2613(c)(1)(C). Those generic names must meet the requirements of TSCA § 14(c)(1)(C), as well as EPA guidance, and many current generic names on the Inventory do not all meet those requirements.

Under TSCA § 14(c)(1)(C), all generic names must:

> (i) be consistent with guidance developed by [EPA] under paragraph (4)(A); and
> (ii) describe the chemical structure of the chemical substance as specifically as practicable while protecting those features of the chemical structure—
>
> (I) that are claimed as confidential; and
>
> (II) the disclosure of which would be likely to cause substantial harm to the competitive position of the person.

15 U.S.C. § 2613(c)(1)(C). Thus, when asserting a claim for confidentiality for specific chemical identity, the claimant must propose a generic name that "describe[s] the chemical structure of the chemical substance as specifically as practicable," and the claimant may only seek nondisclosure of those features that "are claimed as confidential" and "the disclosure of which would be likely to cause substantial harm to the competitive position of the person." *Id.* In addition, the generic name must be consistent with the Guidance EPA developed pursuant to TSCA § 14(c)(4)(A).

While EPA already has listed generic names for the chemicals on the Inventory, not all of those generic names meet the requirements of TSCA § 14(c)(1)(C). Thus, EPA should require claimants to submit generic names along with a certification that the generic name meets the requirements of TSCA § 14(c)(1)(C). Specifically, the claimant should certify that the generic name "describe[s] the chemical structure of the chemical substance as specifically as practicable." *Id.* In addition, claimants must claim specific features of the chemical as confidential and those features may only be those "the disclosure of which would be likely to cause substantial harm to the competitive position of the person." *Id.*

In the Guidance promulgated under TSCA § 14(c)(4)(A), EPA has already committed to reviewing generic names when receiving claims for confidentiality for specific chemical identity. *See* U.S. EPA, Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under the Toxic Substances Control Act at p.2, https://www.epa.gov/sites/production/files/2018-06/documents/san6814_guidance_for_creating_tsca_generic_names_2018-06-13_final.pdf ("Also consistent with the TSCA Section 14(c)(4) and (c)(1)(C) requirements, EPA will be reviewing generic names upon receipt in TSCA filings where chemical identity is claimed as confidential for consistency with the guidance."). EPA should clarify that it will also be reviewing the generic names of these chemicals as part of its review of the confidentiality claims under the review plan.

As a matter of law, EPA must review the generic names as part of this process. As explained above, TSCA requires the assertion of the generic name as part of asserting any confidentiality claim for specific chemical identity, and implicit in the review of any such confidentiality claim is review of that generic name as well, since it is part of the assertion of the claim. In addition, TSCA § 8(b)(4)(D)(ii)(III) expressly requires that EPA consider each confidentiality claim and "approve, approve *in part* and deny *in part*, or deny each claim." 15 U.S.C. § 2607(b)(4)(D)(ii)(III) (emphases added). Thus, Congress clearly contemplated that EPA would sometimes partially grant and partially deny confidentiality claims for specific chemical identity, and as a practical matter, such partial rulings could be used to require changes to the generic name to reveal those parts of the specific chemical identity for which EPA denies confidentiality.

A. Companies should provide a statement explaining how the generic name meets the required criteria of TSCA § 14(c)(1)(C).

EPA should direct companies submitting generic names to provide a statement explaining how the generic name meets the required criteria of TSCA § 14(c)(1)(C), including compliance with the Guidance. Such a statement would assist EPA in its review of the generic names, and it would better ensure that the companies have carefully considered and followed these requirements. Such a statement has some precedent in EPA's practices, since EPA's original Guidance on Generic Names stated that: "Although the guidelines illustrate the masking of a single structural feature, multiple masking is permitted *if the company reporting the substance justifies in writing the need for such additional masking*." U.S. EPA, TSCA Inventory: 1985 Edition Volume I, App. B at p. 983 (Jan. 1986), https://www.epa.gov/sites/production/files/2015-08/documents/genericnames.pdf (hereinafter "1985 Guidance on Generic Names") (emphasis added). Now that Congress has added additional requirements for generic names, it makes sense for EPA to expand this direction for written justification to cover all generic name submissions accompanying claims made through the Inventory notification and review plan processes.

Such a statement is effectively necessary since companies may only request nondisclosure of "features" "that are claimed as confidential." 15 U.S.C. § 2613(c)(1)(C)(ii)(I). To effectuate this requirement, EPA needs to create a clear procedure for companies to assert which specific features are claimed confidential (submission of a generalized claim for confidentiality for the specific chemical identity does not suffice to fulfill this requirement, which requires that the specific "features" be "claimed as confidential"). Thus, as a practical matter, companies need to submit a statement addressing the TSCA § 14(c)(1)(C)(ii)(I) criterion to comply with this provision.

In addition, EPA should request that companies address the other requirements of TSCA § 14(c)(1)(C) to assist with EPA's review. From a practical perspective, the company will need to provide its reasons for asserting that disclosure of those specific features "would be likely to

cause substantial harm to the competitive position of the person." *Id.* It will be exceedingly difficult for EPA to review this aspect of the claim without input from the company, and EPA should not engage in speculation or guesswork.

Finally, it would undoubtedly assist EPA with its review if the company has addressed how the generic name complies with the statutory requirement that it "describe the chemical structure of the chemical substance as specifically as practicable." 15 U.S.C. § 2613(c)(1)(C). EPA should require that companies provide their reasons for believing that the generic name meets this requirement as well.

B. EPA should analyze the generic name carefully when reviewing the confidentiality claim for a specific chemical identity and should address the appropriateness of the generic name in any final approvals.

As described above, EPA must review "all" confidentiality claims for specific chemical identities made through this review process. During review, EPA must review the claimant's substantiation and deny any claim for confidentiality that does not meet the requirements of TSCA § 14(c)(1)(B). Under TSCA § 26(j), EPA must make its confidentiality determinations available to the public. *Id.* § 2625(j)(1).

If EPA concludes that a claimant has established that the specific chemical identity meets these criteria, then EPA should also reexamine the generic name for compliance with TSCA § 14(c)(1)(C). It makes sense to review the generic name at this stage because, as part of reviewing the overall confidentiality claim, EPA will have analyzed whether "disclosure of the information is likely to cause substantial harm to the competitive position of the person." 15 U.S.C. § 2613(c)(1)(B)(iii). If EPA concludes that such harm is likely, then EPA should at the same time consider whether the generic name only conceals "features *** the disclosure of which would be likely to cause substantial harm to the competitive position of the person." *Id.* § 2613(c)(1)(C)(ii)(II).

If, at this stage, it becomes clear that a more specific generic name is appropriate, EPA should first seek to reach agreement with the claimant on the appropriate generic name. Ultimately, EPA can rely on its authority under TSCA § 14(g) to "approve in part and deny in part" the confidentiality claim by requiring a generic name that describes the substance more specifically. 15 U.S.C. § 2613(g)(1)(A).

As a matter of transparency and good government, when determining whether a specific chemical identity meets the requirements for nondisclosure under TSCA § 14, EPA should also determine whether its generic name meets the requirements of TSCA § 14(c)(1)(C). EPA should make both determinations publicly available under 15 U.S.C. § 2625(j)(1), recognizing that portions of the analysis may need to be redacted consistent with TSCA § 14.

11. To the extent EPA grants claims for confidentiality for specific chemical identity, EPA must assign unique identifiers to each such chemical.

TSCA § 14(g)(4) requires that EPA "shall develop a system to assign a unique identifier to each specific chemical identity for which the Administrator approves a request for protection from disclosure, which shall not be either the specific chemical identity or a structurally descriptive generic term." 15 U.S.C. § 2613(g)(4)(A)(i). EPA must then "apply that identifier consistently to all information relevant to the applicable chemical substance." *Id.* § 2613(g)(4)(A)(ii).

EPA must comply with these duties with respect to each chemical substance where EPA approves a confidentiality claim through the CDR process. EPA's current proposal acknowledges this duty in the preamble, and EPA should incorporate it into its confidentiality provisions.

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EDF appreciates the opportunity to provide comments and EPA's consideration of them.