



**Environmental Defense Fund Comments on
TSCA Chemical Data Reporting Revisions and
Small Manufacturer Definition Update for
Reporting and Recordkeeping Requirements
Under TSCA Section 8(a)
Docket ID: EPA-HQ-OPPT-2018-0321¹**

Submitted June 24, 2019

Environmental Defense Fund (EDF) appreciates the opportunity to provide comments on EPA’s proposed rule, “TSCA Chemical Data Reporting Revisions and Small Manufacturer Definition Update for Reporting and Recordkeeping Requirements Under TSCA Section 8(a).” 84 Fed. Reg. 17,692 (April 25, 2019).

These comments address numerous aspects of EPA’s proposal. We identify certain provisions EDF supports, with modifications, as critical to ensure EPA can more effectively and efficiently review confidential business information (CBI) claims asserted through the CDR, and to enhance the utility and granularity of information reported under the CDR.

With respect to provisions that address companies’ ability to claim, and EPA’s review of claims for, confidentiality, changes are needed to fully incorporate statutory requirements limiting such claims and to clarify EPA’s obligations to disclose both information that does not warrant confidential status under TSCA and its determinations on CBI claims. In particular, EPA must codify the correct substantive criteria for review of confidentiality claims, which include those under amended TSCA as well as FOIA. EDF identifies a number of changes needed to EPA’s proposed substantiation questions to ensure conformance with the law and a recent Court decision, and to better ensure EPA’s ability to review and make appropriate determinations on CBI claims. EPA also needs to add provisions to ensure that chemicals with confidential identities are assigned unique identifiers and appropriate generic names.

With respect to proposed modifications to reportable data elements, EDF generally supports EPA’s proposals but identifies changes needed to ensure optimal reporting and public access to

¹ Available at <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0321-0001>.

CDR information. EPA also needs to expand its reporting of information relevant to determining the nature and extent of chemicals exposures to children.

EPA has proposed major expansions of exemptions for byproduct reporting that EDF opposes and believes are both overbroad and will severely constrain EPA’s ability to obtain information it needs to carry out its duties under TSCA, including its chemical prioritization, risk evaluation and risk management responsibilities. EPA should also revisit, rather than merely codify by rote, existing CDR exemptions.

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1. Changes are needed to the proposal’s confidentiality provisions to conform to amended TSCA and ensure EPA can effectively and efficiently review CBI claims under the CDR.

A. EPA needs to incorporate into its regulation additional statutory provisions that limit confidential business information.

EDF supports EPA’s proposal to incorporate TSCA’s exclusions from CBI eligibility for general information on chemicals’ processes, functions and uses identified in TSCA § 14(b)(3)(B). EPA proposes to codify these exclusions at section 711.30(a)(iii).

However, EPA also needs to incorporate three additional TSCA provisions that delineate ineligibility for or time limits on CBI protection:

- TSCA § 14(b)(3)(A)’s general volume information provision that provides the authority for EPA to publicly report such information “expressed as specific aggregated volumes or, if the Administrator determines that disclosure of specific aggregated volumes would reveal confidential information, expressed in ranges;” and
- TSCA § 14(e)(1)(B)’s limit on the duration of most CBI claims to 10 years unless the claimant is granted an extension pursuant to § 14(e)(2). In the preamble EPA states it has not included this provisions because, even though it applies to claims in information reported under the CDR, the limitation “does not distinctively impact the CDR data collections” (p. 17698/1).² However, elsewhere in the proposed rule, EPA incorporates other TSCA provisions that are not CDR-specific – for example, the substantiation requirement, which is proposed to be codified at section 711.30(a)(3). EPA will still need to implement these duties when processing submissions made through the CDR, so it makes sense for EPA to codify them into the regulations governing the CDR. Moreover, in its proposal of Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (hereinafter, “Proposed Review Rule”), EPA correctly codifies this 10-year limitation. *See* 84 Fed. Reg. 16,826, 16,833 (proposed Apr. 23, 2019) (to be codified at 40 C.F.R. § 710.55(b)). As a general matter, EPA should strive to make the confidentiality provisions of these two rules consistent and coherent with each other.
- TSCA § 14(e)(1)(B)’s other limits on the duration of protection for confidentiality. Specifically, TSCA § 14(e)(1)(B)(ii) provides that protection for confidentiality claims ends if “(I) the person that asserted the claim notifies [EPA] that the person is withdrawing the claim, in which case the information shall not be protected from disclosure under this section” or “(II) [EPA] becomes aware that the information does not

² Throughout these comments, we make specific references to the Federal Register notice for the proposed rule as follows: (page number/column number).

qualify for protection from disclosure under this section, in which case [EPA] shall take any actions required under subsections (f) and (g).” 15 U.S.C. § 2613(e)(1)(B)(ii). As above, EPA correctly codified this limit on the duration of claims in its Proposed Review Rule. 84 Fed. Reg. 16,826, 16,833 (to be codified at 40 C.F.R. § 710.55(b)). EPA should codify the same provision in the CDR.

B. EPA must disclose information when it receives no claim or a deficient claim, or denies a confidentiality claim.

i. EPA must disclose information when no claim of confidentiality or substantiation is submitted with the information.

In the proposed rule, EPA states that “[i]nformation not asserted as confidential in accordance with the requirements of this section *may* be made public without further notice to the submitter.” 84 Fed. Reg. at 17,727 (to be codified at 40 C.F.R. §711.30(i)) (emphasis added). The “may” should be a “shall.” When EPA receives no confidentiality claim for particular information, then EPA has no statutory basis for withholding the information from the public. Congress created an intricate regime for the maintenance of confidentiality claims, and the purpose of the Lautenberg Act’s amendments to these provisions was to generally increase the public disclosure of information by EPA. It would contravene Congress’s intent for EPA to withhold information when no confidentiality claim accompanies the information.

Similarly, failure to substantiate should lead to disclosure of the information claimed confidential (except for those claims subject to an exemption under TSCA § 14(c)(2) from the substantiation requirement). When a claimant fails to substantiate a claim, EPA *must* disclose the information because the confidentiality claim cannot be upheld without substantiation. EPA made a statement partially along these lines in the Proposed CBI Review Plan Rule, where EPA stated that if no substantiation were received with a confidentiality claim then “EPA will consider the confidentiality claim as deficient.” 84 Fed. Reg. 16,826, 16,833 (proposed Apr. 23, 2019) (to be codified at 40 C.F.R. § 710.49). As noted above, EPA should strive to make these two rules more consistent and coherent with each other. EPA should codify a similar provision in the CDR Rule, though EPA should change the statement that it “may” disclose the information to a “shall” disclose the information because EPA has no basis to withhold information when there is no substantiation of the confidentiality claim.

The Lautenberg Act specifically requires that: “[e]xcept as provided in [§ 14(c)(2)], a person asserting a claim to protect information from disclosure under this section *shall* substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section.” 15 U.S.C. § 2613(c)(3) (emphasis added). EPA has recognized and announced that this provision of law requires contemporaneous substantiation when making a confidentiality claim. 82 Fed. Reg. 6522 (Jan. 19, 2017). 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. Such deficient claims should be denied and the associated information made public.

Moreover, as discussed more below, Congress specifically amended the confidentiality provisions of TSCA to ensure greater public access to information; the requirement that all persons substantiate their confidentiality claims serves that purpose. If EPA fails to disclose information without any substantiation, EPA will be contravening Congress's entire purpose in making these revisions to TSCA § 14. EPA cannot adopt an interpretation of the Act which defeats Congress's purpose.

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

Under TSCA § 14(g)(1)(A), EPA must review all claims for confidentiality for specific chemical identity submitted through the CDR process³ as well as a representative subset, comprising at least 25 percent, of all other claims for confidentiality. 15 U.S.C. § 2613(g)(1)(A), (C). If EPA denies a claim, EPA must notify the claimant and provide the claimant 30 days to challenge a denial. *Id.* § 2613(g)(1)(D), (2). In this proposed rule, EPA should address these steps, as well as 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 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 disclosing that information to the public. More broadly, 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.

C. EPA needs to exclude two reporting elements from CBI eligibility that constitute health and safety information that is not protected from disclosure under TSCA.

TSCA's definition of the term "health and safety study" includes "any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical

³ TSCA § 14(g)(1)(C)(i) requires that EPA review all claims for confidentiality for specific chemical identity "except with respect to information described in subsection (c)(2)(G)." 15 U.S.C. § 2613(g)(1)(C)(i). Subsection (c)(2)(G) only exempts chemicals "[p]rior to the date on which a chemical substance is first offered for commercial distribution." *Id.* § 2613(c)(2)(G). As a practical matter, chemicals reported through the CDR have all been offered by commercial distribution, and thus EPA must review all confidentiality claims for specific chemical identity made through the CDR.

substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter.” 15 U.S.C. § 2602(8). As a general rule, health and safety studies and their underlying information cannot be withheld from disclosure under TSCA § 14(b)(2). 15 U.S.C. § 2613(b)(2).⁴

EPA codified and expanded on the definition of health and safety study at 40 C.F.R. § 720.3(k), specifically including: “(iii) Assessments of human and environmental exposure, including workplace exposure” and “(iv) Monitoring data, when they have been aggregated and analyzed to measure the exposure of humans or the environment to a chemical substance or mixture.”

Two CDR reporting elements meet this definition and need to be added to the exceptions list to be codified at section 711.30(a)(2):

- *Number of workers potentially exposed*: EPA has inappropriately identified this reporting element as eligible for CBI protection on the basis that it does not offer a “general description” and hence does not fall under TSCA § 14(b)(3)(B). (p. 17699/3). First, given that reporting is required only in ranges, it certainly qualifies as a general description. Second, such information meets TSCA’s definition of a “health and safety study.” It is a key element of any “assessment of *** workplace exposure” and clearly is a “measure [of] the exposure of humans or the environment to a chemical substance or mixture.” 40 C.F.R § 720.3(k).
- *Presence in or on products intended for use by children*: In its preamble, EPA has appropriately identified this reporting element as ineligible for CBI protection, but only on the basis that it constitutes a “general description” of use and hence falls under TSCA § 14(b)(3)(B). (p. 17699/3). While we agree with this argument, such information also meets TSCA’s definition of a “health and safety study.” It is a key element of any “assessment of human *** exposure” and clearly is a “measure [of] the exposure of humans or the environment to a chemical substance or mixture.” 40 C.F.R. § 720.3(k). However, EPA has failed to incorporate this reporting element into the list of exceptions from CBI protection. EPA needs to add “§ 711.15(b)(4)(ii)(D)” to the list enumerated in section 711.30(a)(2)(iii).

D. EDF largely supports a number of EPA proposals as critical to ensure EPA can effectively and efficiently review CBI claims asserted through the CDR.

EPA’s proposed rule includes several provisions that EDF for the most part supports because they would (and appear intended to) better ensure that substantiations are submitted for all claims requiring them and that those substantiations better address the need for protection from

⁴ There are two narrow exceptions to nondisclosure under TSCA § 14(b)(2), but neither of the types of information described herein qualify for those exceptions.

disclosure for the specific information for which a claim is being asserted. These provisions – and, where applicable, changes that need to be made to them – are listed below.

- In section 711.30(a)(3), EPA proposes to indicate that CBI claims for only three CDR elements do not require substantiations because they fall under TSCA § 14(c)(2): specific production volume, and certain supplier information associated with joint submissions. EDF agrees that these are the only CDR reporting elements that so qualify. However, two changes are needed:
 - In subparagraphs (ii) and (iii), EPA asserts that a chemical’s trade name is among the elements falling under TSCA § 14(c)(2). Yet trade names are not encompassed by specific chemical identity. Trade names are not mentioned among the eligible chemical identifiers denoted in TSCA § 14(c)(2)(G); they are not included in EPA’s online guidance for what elements qualify as exempt in either CDR Form U’s or PMNs;⁵ and by their very nature trade names are shared in commerce. EPA needs to strike these references to trade names in subparagraphs (ii) and (iii) and make clear any CBI claim for trade names is subject to the substantiation and EPA review requirements under TSCA § 14.
 - EPA’s cross references in subparagraphs (ii) and (ii) are incorrect; it appears EPA meant for the cross reference to be to section 711.15(b)(3)(i)(B)(1), (2), and (3).
- In section 711.30(d), EPA proposes that “a submitter may assert a claim of confidentiality for a site, company, or technical contact identity only if the linkage of that information to a reportable chemical substance is confidential and not publicly available.” In the preamble, EPA notes that masking the company identity may not be appropriate where the other elements (site location and/or technical contact) are or could be masked instead. (p. 17699/2). This approach is a good step in the direction of requiring companies to assert more specific claims that protect from disclosure no more information than necessary, and only where they can demonstrate likely competitive harm from disclosure.
- In section 711.30(a)(2)(iii), and in keeping with TSCA § 14(b)(3)(B), EPA proposes to disallow CBI claims for specific CDR reporting elements relating to industrial processing function and use and consumer and commercial function and use. EDF supports these exclusions and their incorporation into EPA’s CDR regulations, as wholly consistent with TSCA.
 - As noted above in subsection C, however, EPA needs to add the number of workers potentially exposed and the presence of a chemical in or on products

⁵ See U.S. EPA, Guidance on completing Chemical Data Reporting Form U and Pre-manufacture Notices, <https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations#guidance> (last visited June 24, 2019).

intended for use by children into its list of exceptions from eligibility for CBI protection.

E. 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). Specifically, 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).

In its current proposal, EPA cross-references the requirements for confidentiality under FOIA Exemption 4, 84 Fed. Reg. at 17,726 (to be codified at 40 C.F.R. § 711.30(a)(1)), 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.

With respect to the requirements for FOIA Exemption 4, as EPA has already stated in the proposed rule, “[i]nformation claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2.” 84 Fed. Reg. at 17,726 (to be codified at 40 C.F.R. § 711.30(a)(1)). Those general FOIA regulations state that information will be treated as confidential if:

- (a) The business has asserted a business 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 special need in a judicial or quasi-judicial proceeding);

(d) No statute specifically requires disclosure of the information; and

(e) Either—

(1) The business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position; or

(2) The 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. 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.” 40 C.F.R. § 2.208(d). 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 at 40 C.F.R. § 2.208(d) does not precisely 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 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 454.

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 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 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 that here counsels in favor of requiring that a person 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). Therefore, 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.

EPA must codify the substantive standard for review of confidentiality claims in this rule, 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.

F. EDF supports some of EPA's proposed modifications to the CDR substantiation questions, but EPA needs to make additions and changes to these questions to fully comply with TSCA § 14.

EPA's proposed modifications to the CDR substantiation questions would improve, with some important caveats, EPA's ability to review CBI claims in compliance with section 14 of TSCA. In the proposed rule, EPA has divided the substantiation questions into a set of questions that apply to (1) all non-exempt claims and sets of questions that apply specifically to claims for: (2) specific chemical identity; (3) company, site and technical contact identity; and (4) processing and use information. 84 Fed. Reg. at 17,726-27 (to be codified at 40 C.F.R. § 711.30(b)-(e)). While EDF supports some of these modifications, EPA needs to make additions and changes to these questions to fully address all the criteria EPA must consider under 15 U.S.C. § 2613(a) and (c)(1)(B)(i)-(iv). Some of these changes are needed to comply with the D.C. Circuit's ruling in *EDF v. EPA*, 922 F.3d 446 (D.C. Cir. 2019), where the Court ruled that EPA must require substantiation of each element of confidentiality claims identified in TSCA § 14(c)(1)(B). *See id.* at 454.

EDF's comments pertaining to each set of questions are presented below.

i. Questions applicable to all non-exempt CBI claims

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). *See* subsection E. While the set of questions that EPA has proposed to apply to all non-exempt claims will better ensure that EPA has some of the information that it needs to review confidentiality claims for consistency with TSCA § 14, EPA needs to make some additions and

changes to the proposed questions to ensure that it has all the information it needs to substantiate the required factors for a confidentiality claim. In particular, EPA modified or removed some of the existing CDR substantiation questions in ways that will likely negatively impact the utility of substantiations that EPA receives and reduce its ability to effectively evaluate the associated claims. These modifications and removals should be reversed or addressed through other changes; because the Lautenberg Act requires that confidentiality claims meet a *higher* standard than they were held to under TSCA prior to the enactment of the Act, EPA has no rational basis for seeking *less* information and imposing a *less* stringent standard for confidentiality claims after enactment of the Lautenberg Act.

First, EPA has proposed removing a question that is relevant to determining whether information is “reasonably obtainable without the business’s consent by other persons (other than governmental bodies) by use of legitimate means,” 40 C.F.R. § 2.208(c). The current question at 40 C.F.R. § 711.30(b)(1)(iii) asks:

Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

“[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). Therefore, the answer to whether the chemical substance has been patented is directly relevant to determining whether information about the substance is reasonably attainable by the public.

EPA should maintain the question about patents and expand it to include patent applications; alternatively, if EPA wants to reduce the overall number of questions, EPA could add patents and patent applications to the list of “public documents” in EPA’s proposed question at 40 C.F.R. § 711.30(b)(3). While EPA’s proposed question in principle should require claimants to identify patents and patent applications, EPA should add them to the list of examples to avoid any potential omissions or inaccurate reporting by claimants.

In addition, for the question proposed at 40 C.F.R. § 711.30(b)(3), EPA has removed “[s]tate, local, or Federal agency public files” from the list of public documents that the claimed confidential information may appear in. EPA should retain references to those documents in the final question 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. § 711.30(b)(3).

Second, 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 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: “Has this information ever been 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.

Third, EPA should ask further questions about the likelihood of substantial harm to competitive position, as it does in its current CDR Rule. In the proposed rule at 40 C.F.R. § 711.30(b)(1), EPA has removed these questions: “How could a competitor use such information? *** What is the causal relationship between the disclosure and the harmful effects?” Without answers to these questions, a company’s explanation of why and how disclosure would likely result in substantial harm will likely 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.⁶ EPA should add these questions to the final rule.

Finally, in section 711.30(b)(5), EPA proposes to require companies to indicate if they need less than 10 years protection for the information they are claiming CBI. In the preamble, EPA notes that wherever companies indicate that less than 10 years protection is needed, it would “enable the information to be made public at that time;” *see* p. 17700/1. EDF supports inclusion of this question in the substantiation questions for all claims subject to the 10-year limit and the substantiation requirement.

⁶ *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).

ii. *Questions applicable to specific chemical identity*

In regards to the questions covering specific chemical identity, EDF supports the proposed questions, but some additions and modifications are necessary.

First, as the D.C. Circuit held in *EDF v. EPA*, EPA must require substantiation that claimed confidential information is not “readily discoverable through reverse engineering.” *EDF v. EPA*, 922 F.3d 446, 454 (2019). Two of the proposed questions in particular – at § 711.30(c)(2) and (3) – are good first steps towards meeting that obligation as required by 15 U.S.C. § 2613(c)(1)(B)(iv) and the mandate in *EDF v. EPA*. EDF strongly supports including these questions in the final rule because they would provide some of the information EPA needs to fulfill its duties under § 2613(c)(1)(B)(iv), but to fully implement the statutory requirement and address the concerns raised by the Court in *EDF v. EPA*, EPA must go a step further.

In order to determine whether the identity of the chemical substance is “readily discoverable through reverse engineering,” EPA should add a follow-up question that directly addresses 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.⁷ 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).⁸ EPA’s substantiation questions must directly address whether these available techniques would 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.

Second, EPA needs to address the following additional issues with one of the proposed questions addressing specific chemical identity, proposed 40 C.F.R. § 711.30(c)(1):

⁷ 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).

⁸ 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).

- EPA has provided only one example in the parenthetical but uses “i.e.” to introduce the example. The example should be introduced with an “e.g.”
- It is also unclear what EPA means by asking “Is this chemical substance publicly known to be in U.S. commerce by a specific chemical identity *or name that is consistent with its listing on the confidential portion of the TSCA Inventory.*” (emphasis added). What precisely is this language trying to determine? Is the language in italics meant to inquire whether the specific name can be identified based on the generic name listed on the Inventory? Or is EPA trying to determine whether the chemical substance is listed on the Inventory? EPA should make its intent clear in the final question.

Third, EPA has proposed to eliminate an important question designed to determine whether the specific chemical identity 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.” 40 C.F.R. § 2.208(c). In the current CDR Rule, EPA asks a straightforward question that enquires into whether *competitors* could have discovered the information, as opposed to just the public at large: “Has the identity of the chemical substance 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 the company’s connection to a specific chemical identity is information meriting confidential protection. In the latter circumstance, the correct approach is to disclose the specific chemical identity on the Inventory and CDR report while concealing 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 standards for confidentiality more demanding, rather than less. EPA has no basis for ceasing to ask this straightforward question here.

iii. Questions applicable to company, site, and technical contact identity and processing and use information

EDF supports the proposed questions for both the company, site, and technical contact identity and the processing and use information. While these mostly remain unchanged from the current CDR, the proposed modifications to 40 C.F.R. § 711.30(d)(1) to include company and technical

contact identity, and to ask whether the information is present in “any public document,” will provide useful information to EPA when evaluating the substantiations. EPA should publish these questions as proposed in the final rule.

G. EPA must ensure adequate public disclosure of its review of confidentiality claims.

- i. 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 CDR submissions, 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 “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.

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

As currently drafted, the CDR rule anticipates that companies may make confidentiality claims in the substantiations supporting confidentiality claims. In particular, the proposed rule correctly requires that persons clearly identify any information subject to confidentiality claims in their substantiations. 84 Fed. Reg. at 17,727 (to be codified at 40 C.F.R. § 711.30(g)). But EPA has not described 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 specifically:

- Require that claimants submit “sanitized” versions of their substantiations which redact the specific information that is claimed confidential at the time they submit those substantiations.
- Require that claimants also 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 15 U.S.C. § 2613(g)(1)(A), (C).

H. To the extent 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 “assert[ing]” claims here. *See* 84 Fed. Reg. at 17,726 (to be codified at 40 C.F.R. § 711.30(a)(1)) (allowing persons to “assert a confidentiality claim”). Under the statute, all confidentiality claims made as part of this CDR process are made pursuant to TSCA § 14(c)(1), allowing the “assertion of claims.” 15 U.S.C. § 2613(c)(1). Therefore, to the extent persons are asserting confidentiality claims for specific chemical identities, 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.

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 would require changes to the generic name to reveal those parts of the specific chemical identity for which EPA denies confidentiality.

- i. Companies asserting confidentiality claims for specific chemical identity must provide a generic name that meets the required criteria of TSCA § 14(c)(1)(C).*

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 under this rule 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 confidential chemicals on the Inventory, not all of those generic names meet the requirements of TSCA § 14(c)(1)(C). Thus, EPA should require claimants under this rule 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* 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 asserted under the CDR.

- ii. *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, 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> (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 CDR.

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.

iii. 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.

EPA must review “all” confidentiality claims for specific chemical identities made through the CDR. *See* 15 U.S.C. §§ 2613(g)(1)(A), (C)(i). 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).

In sum, 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.

I. 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 does not acknowledge this duty, and EPA should incorporate it into its confidentiality provisions.

2. EDF generally supports the proposed modifications to Reportable Data Elements, but some changes and additions are needed.

A. EDF supports EPA’s proposal to enhance the CDR’s processing and use codes.

i. Industrial and consumer/commercial function codes

EDF supports EPA’s proposals to replace the CDR’s processing, function and use codes with OECD function, product, and article use categories and to add OECD function categories for commercial and consumer products. We support the proposed expansion of required reporting of function codes to encompass commercial and consumer products as well as industrial processing and use.

EPA has requested comment on whether to require reporting for all of the OECD functional use codes, including those for non-TSCA uses. EDF supports EPA doing so because exposures from non-TSCA uses add to the baseline exposures that help to determine the extent of risk presented by exposures from the TSCA uses EPA is required to assess and mitigate. Notably, EPA has said that it may consider these non-TSCA uses in its section 6 risk evaluations as background exposures. *See, e.g.*, Procedures for Chemical Risk Evaluation Under the Amended Toxic Substances Control Act, 82 Fed. Reg. 33,726, 33,735 (Jul. 20, 2017). It is therefore critical that EPA collect this information on non-TSCA uses under the CDR.

ii. Commercial/consumer product codes

EPA also proposes to adopt the OECD codes for (separate) lists of product and article categories for reporting of commercial and consumer product information. EDF supports this proposal, as they would provide much-needed greater granularity in the reporting of use information as well

as greater consistency in the chemical use information collected or reported across different jurisdictions.

EPA has requested comment on whether to require reporting for all of the OECD codes, including those for non-TSCA uses. EDF supports EPA doing so because exposures from non-TSCA uses add to the baseline exposures that help to determine the extent of risk presented by exposures from the TSCA uses EPA is required to assess and mitigate.

B. EPA should require reporting of the percentage of production volume recycled.

EPA seeks comment on whether to require reporting of the percentage of production volume recycled, rather than just whether any recycling is occurring, citing several reasons. (p. 17702/2-3). EDF believes EPA should adopt this requirement because of its utility to EPA's development of more robust and granular understandings of chemicals' conditions or use and related potential exposures. Such information may help to inform EPA's prioritization as well as risk evaluation process under TSCA.

Notably, this information would have been directly and immediately applicable to EPA's risk evaluation of hexabromocyclododecane (HBCD), where EPA admitted in the problem formulation that "To date, little is known by EPA about the recycling of EPS and XPS products containing HBCD." U.S. EPA, Problem Formulation for Cyclic Aliphatic Bromides Cluster (HBCD) at pp. 21, 28 (May 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0735-0071>.

In addition to asserting burden reduction benefits, EPA suggests such information would aid the agency in granting reporting exemptions. EPA has not provided a factual basis in its proposal as to why recycling activities inherently warrant such exemptions. The many counter-examples of substantial impacts of chemical exposures arising from recycling activities argue against any preconception that recycling is inherently cleaner or safer; EPA should instead provide a compelling factual basis for any such reporting exemptions it proposes to grant in the future.

C. EPA should require reporting of the percentage of a chemical's total production volume that is in the form of a byproduct.

EPA has proposed to require reporting of the percentage of total production volume that is a byproduct. 84 Fed. Reg. at 17,723 (to be codified at 40 C.F.R. § 711.15(b)(3)(vi)). EDF supports this proposal to the extent it helps EPA to better "understand a larger spectrum of exposure scenarios, by improving understanding of the connection between manufacturing and downstream activities for the purposes of substance life cycle assessments and risk evaluation." (p. 17702/3).

However, EPA's proposal seems primarily motivated by the desire to identify further reporting exemptions for byproducts, apparently based on an unstated assumption that the exposure and risk potential for byproducts is somehow inherently lower than for chemical products. There is no factual basis for this assumption, and EPA needs to provide a compelling factual basis for any such reporting exemptions it proposes to grant in the future. See section 3 of these comments for detail on EDF's serious concerns with both the current and the proposed byproduct exemptions.

D. EPA should require reporting of the specific function of a chemical in imported mixtures.

EPA has proposed to require reporting of the specific function of a chemical in imported mixtures, in addition to information on the chemical composition of the imported mixture or product. 84 Fed. Reg. at 17,723 (to be codified at 40 C.F.R. § 711.15(b)(3)(i)(B)(I)). This information would be reported by the secondary submitter of a joint submission. EPA notes, and provides an example illustrating, that while the product function currently is required to be reported, product function is not necessarily one-and-the-same as the function of a specific chemical in a mixture or the product. EDF supports EPA's proposal to add this reporting requirement.

E. EPA needs to broaden the CDR reporting element pertaining to the use of chemical substances in products to which children could be exposed.

The 2016 amendments to TSCA require EPA to identify, evaluate and mitigate risks to "potentially exposed or susceptible subpopulations," a term that is defined as including "infants, children [and] pregnant women." 15 U.S.C. § 2602(12). In light of this new mandate, EPA should expand its requirement for companies to report information germane to understanding the full extent of chemical exposures to these groups.

The current CDR, which focuses only on chemicals in products intended for use by children, captures only a tiny sliver of relevant exposures and is misleadingly narrow. First, CDR reporting is limited to manufacturers, who typically have limited knowledge about whether or how the chemicals they manufacture are used in products intended for use by children; such information need only be reported to the extent it is known or reasonably ascertainable by the manufacturer.

Second, even if a product is not intended for use by children, it may very well be used by them. Children are also often subject to exposures as bystanders even if they are not themselves using a product. Further, unintentional or accidental exposures are important to consider. For example, many children are accidentally consuming laundry detergent pods. According to the American

Association of Poison Control Centers, there were nearly 12,000 cases of laundry detergent pod exposure in children five years old and younger reported to poison centers in 2014.⁹

Finally, an approach that relies exclusively on use of chemicals in children's products completely ignores prenatal exposures, which can be as or even more detrimental than exposure during childhood.¹⁰ EPA's own framework for assessing health risks to children applies a lifestage approach, including preconception and prenatal exposures: "Assessing potential health risks to children as a result of their environmental exposure to toxicants includes considering risk from exposure before conception, during the prenatal period, and through childhood and adolescence."¹¹

EPA should make several changes to its reporting of information relevant to children's exposures under the CDR:

- Expand reporting to include identification of chemical substances known or reasonably ascertainable to be used in products:
 - children may use, regardless of whether the products are intended for use by children;
 - children may be exposed to as bystanders; and
 - pregnant women may be exposed to.
- Expand reporting to include processors of any such chemical substance. TSCA gives EPA full authority to require reporting by processors. The CDR is promulgated under the authority of TSCA section 8(a)(1), which provides for EPA to "promulgate rules under which *** each person *** who manufactures *or processes*" a chemical substance *** shall submit to [EPA] such reports, as [EPA may reasonably require]." 15 U.S.C. § 2607((a)(1)(A); emphasis added.

3. EPA needs to revisit its current exemptions for reporting of byproducts to align with amended TSCA, and its proposals for further exemptions are highly problematic.

EPA has proposed major expansions of the already extensive exemptions from CDR reporting available for manufacturers of byproducts that it proposes to retain in their entirety. EDF opposes these proposals and believes they are both overbroad and will severely constrain EPA's

⁹ AAPCC, *AAPCC Position Statement on Single-Load Liquid Laundry Packets*, https://aapcc.s3.amazonaws.com/files/library/AAPCC_Laundry_Packet_Position_Statement.pdf.

¹⁰ David C. Bellinger, *Prenatal Exposure to Environmental Chemicals and Children's Neurodevelopment: An Update*, 4:1 SAFETY & HEALTH AT WORK 1 (2013), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3601292/>.

¹¹ U.S., EPA, ORD, *A Framework for Assessing Health Risks of Environmental Exposures to Children* at 2-3 (Sept. 2006), <https://cfpub.epa.gov/ncea/risk/recordisplay.cfm?deid=158363>.

ability to obtain information the agency needs to carry out its duties under TSCA, including making sound decisions with respect to its expanded responsibilities for chemical prioritization, risk evaluation and risk management.

A. EPA should revisit, rather than merely codify by rote, existing CDR exemptions.

Among its “General Regulatory Text Updates,” EPA proposes to incorporate into the regulatory text at § 711.10(c) numerous current exemptions that predate the 2016 amendments to TSCA. Many of these date back to the 1977 rule establishing the original TSCA Inventory, 42 Fed. Reg. 64,572, 64,577 (codified at 40 C.F.R. § 710.4(d)(1)-(7)), and were accompanied then by scant justification. 42 Fed. Reg. at 64,572-75 (offering no explanation for the exemptions in the preamble); *see* 42 Fed. Reg. 39,182, 39,186 (proposed Aug. 2, 1977) (providing scant explanation of the basis for the exemptions); *see also* 48 Fed. Reg. 21, 722 (May 13, 2019) (incorporating the exemptions into the section 5, Premanufacture Notification process, without explanation). Continuation of all of these exemptions is even harder to justify in light of the TSCA amendments that greatly expanded EPA’s duties to prioritize and evaluate the risks of chemicals under their conditions of use. Most or all of the exemptions apply to activities that TSCA now defines to be conditions of use of a chemical substance.¹²

TSCA § 3(4) defines “conditions of use” expansively to “mean[] the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(2). This definition clearly encompasses a chemical’s existence, for example, as a byproduct or impurity. It applies across all stages of the lifecycle, including burning a chemical as fuel or disposing of it as a waste. EPA has no legal basis for treating these conditions of use as less important than a chemical substance’s other conditions of use. These conditions of use also are sources of exposure and risk for chemical substances, so EPA must analyze them to accurately evaluate the risks presented by a chemical substance. As EDF has previously argued in its comments on EPA’s problem formulations for the first 10 chemicals undergoing risk evaluations under TSCA, to fulfill its obligations EPA must analyze all conditions of use of a chemical substance.

Under the Lautenberg Act EPA is also tasked with evaluating whether a chemical substance presents an unreasonable risk to a “potentially exposed or susceptible subpopulation.” 15 U.S.C. § 2605(b)(4)(A). The term “potentially exposed or susceptible subpopulation” is broadly defined in the statute, and includes, but is not limited to “infants, children, pregnant women, workers, or the elderly.” 15 U.S.C. § 2602(12). The exemptions EPA proposes to retain under the CDR will limit the information available to EPA to determine if there are unreasonable risks to potentially

¹² Here EDF is specifically referring to the exemptions in the proposed rule at 40 C.F.R. § 711.10(c)(1) and (c)(4).

exposed or susceptible populations. EPA needs to address this limitation when it revisits these exemptions.

If EPA simply blindly retains all of these prior exemptions, then EPA's failure to obtain information on these conditions of use through the CDR will create data gaps that will severely hamper EPA's ability to analyze these chemicals as required by TSCA when prioritizing chemicals, conducting risk evaluations, and deciding on appropriate risk management. EPA's current problem formulations are fatally flawed because EPA refuses to analyze the exposures and resulting risks flowing from chemicals' releases to the environment – which sometimes result from activities EPA is proposing to continue to exempt from CDR reporting.¹³

EPA needs to review these previously developed exemptions against the new requirements and data needs of TSCA as reformed in 2016 by the Lautenberg Act. The agency needs to carefully consider whether any such exemption is still justified and whether it will hamper the agency's ability to obtain the information it needs to make decisions based on the best available science and considering all reasonably available information, as required by TSCA § 26(h) and (k). 15 U.S.C. § 2625(h), (k). EPA then needs to provide a justification for any such exemption it intends to continue, and provide an opportunity for public comment on that justification.

B. EPA should not provide an option to report by category for some inorganic byproducts.

EPA has proposed to give companies manufacturing certain metal-containing compounds as byproducts to combine multiple such compounds into a designated category of compounds for reporting. 84 Fed. Reg. at 17,722 (to be codified at 40 C.F.R. § 711.15(b)(3)(i)(A)). Companies could opt to do so, or report the compounds individually as has been the case.

In addition, under the category reporting approach, EPA proposes that the determination of whether the reporting threshold is met is to be based on the sum of the total weights of each of the compounds being reported under the category; however, the actual amount *reported* under the category would be only the sum of the weights of the parent metal portion of each compound.

EDF strongly opposes these proposals, for a number of reasons.

First, EPA has not demonstrated why it is significantly more burdensome to continue the current requirement to report such compounds individually. Under the category options, for a company to make the reporting threshold determination as well as to determine the amount to be reported

¹³ See, e.g., EDF Comment on Ten Problem Formulations, EDF Comment on First Ten Problem Formulations at pp. 39, 44-45 <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0066>.

under the category, it would already have to have identified and determined the total weight and metal weight portion of each of the compounds in the category separately. The difference in burden between separately reporting that already determined information for each compound, versus adding it up and reporting it for the category, would seem to be trivial.

Second, EPA has not explained how such an option would be consistent with other provisions of its current or proposed rule:

- If one compound that would fall into a category exceeds the reporting threshold but other compounds the company makes at the same site that would fall in that same category do not, if the company opts to report by category which compounds would need to be added up and reported? Only the one that exceeds the threshold or all of the compounds?
- Given EPA's proposal to require reporting of the percentage of total production volume that is a byproduct—which is to be reported on a chemical-specific basis—how would this be possible if the byproduct is instead being reported as part of a category? This problem would be made even more intractable and any reported information resulting from it even less meaningful, given that EPA would not know which specific compounds are included in the category.

Third, EPA has not explained, and seems not to have considered the effect of this approach on, its ability to make public meaningful aggregate volumes if some companies making a particular compound report it using a category and other companies report it as the individual substance. In such cases, the actual aggregate volume of an individual compound will not be discernible because even a volume aggregated across those companies that reported the compound individually will exclude the amounts of the compound made by those companies that reported it under a category. EPA and the public will lose access to important information as a result, and uncertainty associated with the CDR data will increase.

Fourth, this option provides companies with a means to avoid reporting the identities of compounds they make—by hiding them within a category—even if those substances are already public on the TSCA Inventory and hence not eligible to be withheld from the public.

Fifth, the CDR information resulting from this approach will be far less useful to EPA should it seek to initiate activities leading to prioritization or risk evaluation of one or more of the compounds that fall within a category. While EPA has stated that chemicals would become ineligible for category reporting upon being subject to prioritization or risk evaluation, 84 Fed. Reg. at 17,722 (to be codified at 40 C.F.R. § 711.15(b)(3)(1)(A)), EPA would have no ability to use past CDR information to analyze trends in production, processing and use of a specific chemical over time. (Indeed, this approach will more broadly preclude EPA's and the public's ability to compare new CDR information to prior reporting for any category compounds.) In addition, the lumping-together of production, processing and use information on a group of

compounds that may have significantly different individual uses, exposures and hazards, will greatly hamper EPA's ability to make high-quality decisions with regard to TSCA's prioritization, risk evaluation and risk management processes.

Sixth, as EPA notes some qualifying compounds will contain multiple metals. While EPA argues that they would need to be reported under multiple categories, the result will be duplicative reporting that does not provide an accurate estimate of actual production either of individual compounds or categories.

C. EPA needs to modify its proposed petition process for request changes to the list of exempted processes and related byproducts, including to provide for public notice and comment.

EPA is proposing to add a petition process for persons to request changes (whether additions, deletions or modifications) be made to the list of exempted processes and related byproducts. While EDF does not oppose this proposal, decisions to make any such changes need to be subject to public notice and a public comment opportunity. EPA's preamble discussion and proposed rule text are unclear on this, however. The provision states: "*As needed*, the Agency will initiate rulemaking to make revisions to the list" of exempted byproduct substances. 84 Fed. Reg. at 17,721 (to be codified at 40 C.F.R. § 711.10(c)(2)(ii)(C)) (emphasis added). As drafted, this provision seems to leave to EPA's discretion whether rulemaking is needed. The provision needs to be rewritten to make clear that a) changes to the list must be made through rulemaking, and b) such rulemaking must provide for public notice and a public comment opportunity.

In the preamble, EPA lists two "considerations" that it states must be met by a chemical byproduct in order for it to be considered for addition to the list of exempted substances:

These byproducts would be exempted from reporting only when (1) they are recycled or otherwise used to manufacture another chemical substance within an enclosed system, within the same overall manufacturing process, and on the same site as that byproduct was originally manufactured *and* (2) when the site is reporting under CDR the byproduct substance or a different chemical substance that was manufactured from the byproduct or manufactured in the same overall manufacturing process. (p. 17708/1, emphasis added)

In codifying these requirements at § 711.10(c)(2)(ii)(B), EPA needs to clarify that both requirement must be met. As proposed, the two specifications are listed only as factors to be considered and are not linked with an "and" as they are in the preamble.

D. EPA should not exempt byproducts generated by specified non-integral processes.

EPA is proposing to exempt byproducts manufactured in, or through the use of, pollution control equipment or boilers that generate heat or electricity on-site, when such equipment is not integral to the main production process. (p. 17709/3).

EPA provides two rationales for this proposed exemption, neither of which provide a sufficient basis for the exemption. First, EPA states: “Release from pollution control equipment can often be obtained through national inventories such as TRI.” Even to the extent this is the case for a given chemical, the TRI requires reporting of vastly fewer chemicals (ca. 600) than are reported under the CDR (8,700 chemicals in 2016).

In addition, EPA has itself recognized the major differences between both the information collected under and the purpose of the CDR and TRI programs. In 2011, in finalizing an earlier set of modifications to the CDR (which at that time was called the Inventory Update Reporting (IUR) Rule) EPA addresses questions about the extent of overlap between the TRI and IUR:

The TRI program goal is to provide communities with information about toxic chemical substance releases and waste management, and the TRI reporting requirements are designed to address that goal. Because the IUR program goals differ, the specific information collected under each program is not the same. Where a person must report for both for the same site, EPA and the public will have a broader picture of the exposure scenarios at that site, including environmental releases from that site; while the two information collections may be complementary, neither is an adequate substitute for the other.

76 Fed. Reg. 50816, 50850 (Aug. 16, 2011).

Second, EPA states that, in assessing environmental releases, it uses CDR data as input to general exposure scenarios such as the OECD’s Emission Scenario Documents (ESDs). EPA asserts that, because the ESDs do not include emissions from non-integral equipment, such data need not be reported under the CDR for EPA to be able to utilize the ESDs. But this means the ESDs – and EPA – are excluding real-world releases and the associated exposures to such chemicals. A deficiency in the ESDs cannot be used as the basis to ignore a known environmental release of a chemical or an exemption from reporting under the CDR.

EDF opposes EPA’s proposed exemption.

E. EPA should not continue to exempt byproducts disposed as waste.

EPA has proposed incorporating into the regulatory text an exemption for byproducts that are disposed of as waste, including in a landfill or for enriching soil, *see* 84 Fed. Reg. at 17720 (to be codified at 40 C.F.R. § 711.10(c)(1)(ii)), an exemption that is in the Pre-manufacture Notice regulations and incorporated by reference in the current CDR regulations. *See* 84 Fed. Reg. at

17710 (explaining that the CDR regulations previously referenced the exemptions at 40 C.F.R. § 720.30(g), (h)).

As noted previously, TSCA § 3(4) defines “conditions of use” expansively to “mean[] the circumstances, as determined by [EPA], under which a chemical substance is intended, known, or reasonably foreseen to be manufactured, processed, distributed in commerce, used, or disposed of.” 15 U.S.C. § 2602(2). This definition clearly encompasses a chemical’s existence as a byproduct and its disposal. EPA has no legal basis for treating the disposal of a byproduct as less important than a chemical’s other conditions of use. As EDF has previously argued in its comments on EPA’s problem formulations, to fulfill its obligations under TSCA, EPA must analyze all conditions of use including the disposal of a chemical substance. EPA’s failure to obtain information on these conditions of use will create data gaps that will severely hamper EPA’s ability to analyze these chemicals as required by TSCA. EPA’s current problem formulations are fatally flawed because EPA refuses to analyze the exposures and resulting risks flowing from chemicals’ disposal.

In § 711.10(c)(1), EPA refers to byproducts that are disposed of as waste. Yet the meaning of both “disposed” and “waste” are far from clear and could potentially be very broadly construed to encompass many activities that clearly constitute conditions of use and that can lead to environmental releases and exposures about which EPA will need to have robust information in order to meaningfully evaluate potential risks of a chemical under TSCA.

As one example of the data gaps that will result from failing to require reporting of the disposal of byproducts, EPA will have inadequate information about the chemical’s disposal as a biosolid. A recent EPA Inspector General report details EPA’s lack of adequate data, tools, staff, and resources to make sound determinations on the safety of pollutants found in biosolids applied to land. *See* U.S. OIG, EPA Unable to Assess the Impact of Hundreds of Unregulated Pollutants in Land-Applied Biosolids on Human Health & the Environment (2018), https://www.epa.gov/sites/production/files/2018-11/documents/epaoig_20181115-19-p-0002.pdf. The proposed CDR exemption for byproducts disposed of through land application would deny EPA and the public access to what could be a key source of information on the nature and extent of these activities potentially for thousands of chemicals, and is a missed opportunity to help to fill a major data gap identified by the EPA OIG.

In the problem formulations for several of the first 10 chemicals undergoing risk evaluations under the amended TSCA, EPA has stated its intent to exclude exposures to the chemicals when present in biosolids—despite having no actual information about this release and exposure pathway—because EPA *may* at some point in the future regulate the biosolids under the Clean Water Act. *See, e.g.*, U.S. EPA, Problem Formulation of the Risk Evaluation for Perchloroethylene (Ethene, 1,1,2,2-Tetrachloro) at p. 61 (May 2018),

<https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0732-0080>; U.S. EPA, Problem Formulation of the Risk Evaluation for Carbon Tetrachloride (Methane, Tetrachloro-) CASRN: 56-23-5 pp. 49-50 (May 2018), <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2016-0733-0068>. As EDF has argued elsewhere,¹⁴ such an exclusion from EPA's risk evaluations is both scientifically unsound and counter to TSCA's requirements. Given EPA's repeated acknowledgment of the importance of information collected through the CDR data to EPA's prioritization and risk evaluation activities under TSCA, it is foolhardy for EPA to continue an exemption that will perpetuate the dearth of information available on this exposure pathway.

Additionally, EPA must consider the impacts of the waste exemption on the agency's ability to address the ongoing national crises surrounding per- and polyfluoroalkyl substances (PFAS). If, through the final CDR rule, EPA purposely permits under-reporting of these chemical substances when they are produced as byproducts and disposed of in the environment, the agency, the public, and the scientific community will be left without what could otherwise be a ready source of critical data on the presence of these chemical substances in the environment. *See, e.g.*, Jane Hoppin, Health Impacts of Emerging Contaminants: A look at GenX and beyond (Apr. 2019), <https://cleanaircarolina.org/wp-content/uploads/2019/04/4-Hoppin-NC-Breathe-Final.pdf> (describing the research that led to discovering the presence of PFAS byproducts in the Cape Fear River); *see also* Comment on the Draft Toxicity Assessments for perfluorobutane sulfonic acid (PFBS) and hexafluoropropylene oxide, https://endocrinedisruption.org/assets/media/documents/GenX_PFBS_Comments_19.01.22.pdf. EPA has committed to using TSCA to address this crisis,¹⁵ and one way to do so would be to utilize the CDR to collect information on PFASs when they are produced as byproducts and disposed of as biosolids/waste.

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

¹⁴ *See* EDF Comment on First Ten Problem Formulations at pp. 48-49, <https://www.regulations.gov/document?D=EPA-HQ-OPPT-2018-0210-0066>.

¹⁵ U.S. EPA, *EPA's Per- and Polyfluoroalkyl Substances (PFAS) Action Plan* at pp. 16-18 (Feb. 2019), https://www.epa.gov/sites/production/files/2019-02/documents/pfas_action_plan_021319_508compliant_1.pdf.