



Environmental Defense Fund
Comments on
Needed Improvements to EPA’s CBI Claim Reviews and Public Access to Information

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In its November 20, 2019, Federal Register notice, EPA announced “a public meeting to engage with interested stakeholders on the implementation of EPA’s TSCA New Chemicals program, including: (1) An overview of EPA’s updated ‘Working Approach’ document that builds upon EPA’s November 2017 ‘New Chemicals Decision-Making Framework: Working Approach to Making Determinations under section 5 of TSCA’; (2) a demonstration of how EPA uses key concepts in the Working Approach to reach certain conclusions and/or make determinations under TSCA section 5(a)(3) using specific case examples; (3) an update on confidential business information (CBI) process improvements and clarifications; and (4) a discussion of EPA’s ongoing efforts and progress to increase transparency.” 84 Fed. Reg. 64,063, 64,063 (Nov. 20, 2019). EPA stated that it would “accept written feedback on these topics in the docket until January 24, 2020.” *Id.* EPA is also accepting written comment on the updated “Working Approach” until February 18, 2020. 85 Fed. Reg. 99 (Jan. 2, 2020).

EDF plans to submit comments on the Working Approach and EPA’s approach to new chemicals by February 18, 2020. In the meantime, EDF provides the following comments on EPA’s recently announced efforts on confidential business information and transparency. EDF, along with other organizations, has also previously submitted a Notice of Intent on September 3, 2019, which outlined many problems with EPA’s approaches to confidentiality and transparency. We have attached that Notice as Appendix A, and we urge EPA to address the issues raised in that Notice.

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1. Legal background: Confidentiality claims must be asserted, substantiated, and reviewed as required by TSCA § 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). Third, and importantly, TSCA § 14(b) identifies certain types of information, such as health and safety studies (discussed in detail in Sections 3.A and 3.B), that *per se* cannot be confidential. 15 U.S.C. § 2613(b). Claims asserted for protection of such information should be rejected outright as ineligible.

For that information that can be claimed confidential under TSCA § 14, 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. Except for those claims exempted by TSCA §14(c)(2) from substantiation, “a person asserting a claim to protect information from disclosure under this section shall substantiate the claim.” 15 U.S.C. § 2613(c)(3). EPA has correctly recognized that substantiation must be submitted at the time when a person asserts a confidentiality claim. 82 Fed. Reg. 6522 (Jan. 19, 2017).

At the third procedural step, EPA must review certain claims and make a determination on the claims. 15 U.S.C. § 2613(g). 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). EPA must also review a representative subset, comprising at least 25 percent, of all other confidentiality claims. *Id.* § 2613(g)(1)(C)(ii).

If EPA denies a 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 or if the appeal fails.

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 has not adequately published its determinations or findings on confidentiality claims.

After years of delay, EPA has published some so-called “determinations” on confidentiality claims.¹ However, EPA’s determinations do not meet the requirements of TSCA §26(j). Under TSCA §26(j), EPA “shall make available to the public—all notices, *determinations*, *findings*, rules, consent agreements, and orders of the Administrator under this subchapter.” 15 U.S.C. § 2525(j)(1) (emphases added). EPA has not made complete determinations publicly available, and EPA has also failed to disclose the findings underlying its determinations. EPA’s conclusory statements are also arbitrary and capricious for failing to provide the reasoned analysis necessary to uphold its conclusions.

First, when Congress required that EPA publish “determinations” in TSCA §26(j)(1), Congress did not state that EPA need only publish its “conclusions” or “results” of its analysis. Congress intended that EPA would publish the analysis and underlying “determinations”—factual and legal—necessary to support its conclusions. Courts often describe their findings on particular matters “determinations,” and courts generally publish the underlying factual and legal determinations necessary to support their ultimate determination. As a general matter, a judicial opinion would not be complete if it simply stated “granted” or “denied,” and in much the same way, EPA’s determinations on confidentiality would not be complete if they simply stated “approve” or “deny.” While EPA has arguably gone one step further by providing a “summary determination rationale,” these boilerplate summaries are effectively no more than a conclusory “approve” or “deny”: When EPA approves a claim, it simply states that “Submission met the requirements of section 14(c) and substantiation adequately supported all CBI claims.”² It is

¹ CBI REVIEW AND FINAL DETERMINATIONS, <https://www.epa.gov/tsca-cbi/statistics-tsca-cbi-review-program#reviews> (last visited Jan. 24, 2020) (hereinafter “Final Determination Spreadsheet”).

² Final Determination Spreadsheet.

impossible to tell from this summary that merely states that EPA has complied with the law whether EPA considered the necessary criteria when analyzing the claim, much less what factual and legal determinations underlie EPA's ultimate conclusions on those criteria. It is also not at all clear from this description that EPA considered TSCA § 14(b)'s requirement that certain information is not eligible for protection from disclosure and must be disclosed under TSCA.

Second, in § 26(j)(1), Congress swept broadly by requiring that EPA make its underlying “findings” public as well as its determinations. For confidentiality claims, EPA must make numerous underlying “findings” to approve or disapprove of the underlying confidentiality claim, and those findings in turn are based on evidentiary and legal “findings” supporting EPA's conclusions. Specifically, EPA must make “findings” on, among other things, whether the confidentiality claimant truly has “a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person” and “a reasonable basis to believe that the information is not readily discoverable through reverse engineering.” 15 U.S.C. § 2613(c)(1)(B). In a recent court decision, the D.C. Circuit made it clear that EPA must actually consider whether the information meets these statutorily required criteria. In *EDF v. EPA*, the D.C. Circuit described the inquiry into a “chemical identity’s susceptibility to reverse engineering” as “a statutorily required criterion.” *EDF v. EPA*, 922 F.3d 446, 454 (D.C. Cir. 2019). In the ruling, 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. In the same way, EPA must consider each of the explicit criteria set forth in TSCA § 14(c)(1)(B). EPA must make “findings” on each of these criteria and publish those findings, including the factual findings underlying those ultimate findings.

Third, agencies are required to engage in reasoned decisionmaking, and as part of that process, agencies must articulate their reasons and findings supporting their conclusions. *See Fox v. Clinton*, 694 F.3d 67, 75 (D.C. Cir. 2012). The requirement for reasoned decisionmaking “indisputably” applies in situations involving agency adjudications, such as the confidentiality determinations required by TSCA § 14. *Id.* “We will not uphold an agency adjudication where the agency’s ‘judgment . . . was neither *adequately explained* in its decision nor supported by agency precedent.’” *Id.* (quoting *Siegel v. SEC*, 592 F.3d 147, 164 (D.C. Cir. 2010)) (emphasis added); *Tripoli Rocketry Ass’n v. BATFE*, 437 F.3d 75, 77 (D.C. Cir. 2006) (“We do not, however, simply accept whatever conclusion an agency proffers merely because the conclusion reflects the agency’s judgment.”) (setting aside agency decision “lack[ing] any coherence” and where court could not “discern” agency’s reasons). The D.C. Circuit has expressly rejected “conclusory assertion[s]” when reviewing agency determinations, *Tripoli Rocketry Ass’n v. BATFE*, 437 F.3d at 83, and since EPA’s analyses amount to “conclusory” assertions, they are arbitrary and capricious.

EPA's conclusory table does not establish that EPA has considered the required criteria, and in fact, the table as a whole strongly suggests that EPA is not actually assessing each of the criteria required by TSCA § 14(c)(1)(B). The table does not once refer to any of those criteria—it does not refer to susceptibility to reverse engineering or substantial competitive harm or whether information must be disclosed pursuant to another federal statute or whether the confidentiality claimant has kept the information confidential. *See* 15 U.S.C. § 2613(c)(1)(B). In fact, for the fully denied claims, the summary rationale is always identical: “One or more information elements claimed were found in a public data source and therefore not entitled to confidential treatment.”³ While EPA is certainly correct that such information does not qualify for protection for confidentiality, EPA is supposed to apply other criteria to the review of confidentiality claims as well.

For example, it appears that EPA has not *once* found that information was susceptible to reverse engineering and denied a claim on that basis. But multiple commercial entities widely advertise that they offer “reverse engineering” services.⁴ 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).⁵ How can it be that *not a single chemical identity* was deemed to present a reasonable basis to believe that it could be discoverable through reverse engineering? It appears that EPA is simply not applying this factor at all. EPA has to publish actual determinations and findings that establish that it is applying the necessary criteria. Notably, many substantiation documents do not even inquire whether the chemical is likely to be susceptible to reverse engineering, so it seems quite likely that EPA did not have a factual basis for analyzing this factor when considering these confidentiality claims. Unless EPA can demonstrate that it actually considered this and the other required criteria, EPA must redo the determinations.

There is some slight ambiguity because EPA occasionally decided for a few confidentiality claims to “Approve-in-part/Deny-in-part,” and for all of those conclusions, EPA provided the following summary rationale: “One or more claims in the submission met the requirements of section 14(c) and the substantiation adequately supported the CBI claim(s). However, the

³ Final Determination Spreadsheet.

⁴ 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 Jan. 24, 2020).

⁵ AVOMEEN ANALYTICAL SERVICES, PRODUCT DEFORMULATION SERVICE, <https://www.avomeen.com/scientific-applications/product-deformulation-service/> (last visited Jan. 24, 2020); EAG LABORATORIES, DEFORMULATION, <https://www.eag.com/services/materials/deformulation/> (last visited Jan. 24, 2020).

submitter failed to demonstrate that one or more claims are entitled to confidential treatment.”⁶ From this rationale, it is impossible to tell why the denied claims failed to be entitled to confidential treatment. In any event, a “determination” that provides no justification for its conclusion does not meet the requirements for publication of a determination and findings under TSCA section 26(j)(1). It also falls far short of the reasoned decisionmaking required by the Administrative Procedure Act.

3. EPA allows confidentiality claims for specific chemical identity in health and safety studies in violation of TSCA § 14(b)(2) and EPA’s own announced policy.

A. TSCA and EPA’s own regulations generally preclude protecting chemical identities in health and safety studies from disclosure.

In the Final Determination Spreadsheet, EPA indicates that it reviewed confidentiality claims for TSCA § 8(e) notices. But EPA failed to apply TSCA § 14(b)(2)’s requirement that such health and safety information is generally not eligible for confidentiality—for information covered by TSCA § 14(b)(2), EPA should have rejected the confidentiality claims outright, rather than reviewing the substantiations and then granting confidentiality. TSCA § 14(b)(2) provides that information is not eligible for confidentiality if it is:

any health and safety study which is submitted under this Act with respect to—

(i) any chemical substance or mixture which, on the date on which such study is to be disclosed has been offered for commercial distribution; or

(ii) any chemical substance or mixture for which testing is required under section 4 or for which notification is required under section 5; and

(B) any information reported to, or otherwise obtained by, the Administrator from a health and safety study which relates to a chemical substance or mixture described in clause (i) or (ii) of subparagraph (A).

15 U.S.C. § 2613(b)(2). The only two narrow exceptions to this disclosure requirement are information “that discloses processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.” *Id.* Otherwise, health and safety information must be disclosed.

As discussed in more detail in section 3.B. below, EPA has issued a policy recognizing that, when the specific chemical identity appears in a health and safety study, EPA will generally disclose that information unless it “explicitly contain[s] process information” or “reveal[s] data

⁶ Final Determination Spreadsheet.

disclosing the portion of the mixture comprised by any of the chemical substances in the mixture.” 75 Fed. Reg. 29,754, 29,756 (May 27, 2010). This policy reflects the statutory requirement that health and safety information be disclosed unless it falls within one of the two narrow exceptions of TSCA §14(b)(2), and this information includes the chemical identity in the health and safety study. EPA’s regulations recognize that “[c]hemical identity is always part of a health and safety study.” 40 C.F.R. § 720.3(k).

In turn, TSCA § 8(e) requires persons to notify EPA of any “information which reasonably supports the conclusion that [a chemical] substance or mixture presents a substantial risk of injury to health or the environment.” 15 U.S.C. § 2607(e). Such information is a health and safety study or information from such a study and therefore must be disclosed under TSCA § 14(b)(2).

Despite these requirements, as discussed in more detail in section 3.B. below, EPA *approved* numerous confidentiality claims for what EPA identified as “[s]pecific chemical identity subject to substantiation requirement” in TSCA § 8(e) notices.⁷ Because (1) only the specific chemical identities for chemicals that have been offered for commercial distribution are subject to substantiation requirements, (2) section 8(e) notices including their specific associated chemical identities are health and safety information,⁸ and (3) section 14(b)(2) clearly applies to health and safety information submitted on chemicals that have been offered for commercial distribution, the confidentiality claims that EPA has reviewed and approved fall squarely under section 14(b)(2), and section 14(b)(2) says such information is not eligible for confidentiality, with a narrow exception for process or mixture-portionality information. The information EPA reviewed and approved should have been deemed ineligible for confidentiality and disclosed immediately, rather than undergoing a review to determine whether protection from disclosure is warranted. Despite this requirement, EPA approved over 20 confidentiality claims for specific chemical identity in TSCA § 8(e) notices (see subsection C below).⁹

B. EPA’s own policy forecloses it from concealing chemical identity in health and safety studies.

As mentioned above, in May of 2010, EPA published in the Federal Register a policy statement notifying stakeholders that, in general, the identities of chemicals in commerce are not eligible for protection as CBI under TSCA when submitted to EPA in the context of a health and safety

⁷ Final Determination Spreadsheet.

⁸ EPA itself has identified Section 8(e) notices as health and safety information. <https://www.epa.gov/tsca-cbi/frequent-questions-about-tsca-cbi#Q15>.

⁹ Final Determination Spreadsheet.

information submission, including a “substantial risk” notice submitted under TSCA section 8(e).¹⁰

That notice stated in part:

EPA will begin a general practice of reviewing confidentiality claims for chemical identities in health and safety studies, and in data from health and safety studies, submitted under the Toxic Substances Control Act (TSCA) in accordance with Agency regulations at 40 CFR part 2, subpart B. Section 14(b) of TSCA does not extend confidential treatment to health and safety studies, or data from health and safety studies, which, if made public, would not disclose processes used in the manufacturing or processing of a chemical substance or mixture or, in the case of a mixture, the release of data disclosing the portion of the mixture comprised by any of the chemical substances in the mixture. Where a chemical identity does not explicitly contain process information or reveal portions of a mixture, EPA expects to find that the information would clearly not be entitled to confidential treatment.¹¹

EPA’s notice further stated:

TSCA Section 14(b)(1) [now section 14(b)(2) in amended TSCA] provides that health and safety studies and data from health and safety studies are not entitled to confidential treatment unless such information, if made public, would disclose processes used in the manufacturing or processing of a chemical substance or mixture or in the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture. (15 U.S.C. 2613(b)(1)).¹²

EPA further cited its own regulations that establish that “[c]hemical identity is part of a health and safety study. See, e.g., 40 CFR 716.3 and 40 CFR 720.3(k).”¹³

Finally, EPA noted the importance of public access to chemical identities in health and safety information:

¹⁰ Claims of Confidentiality of Certain Chemical Identities Contained in Health and Safety Studies and Data from Health and Safety Studies Submitted Under the Toxic Substances Control Act 75 Fed. Reg. 29,754 (May 27, 2010), <https://www.govinfo.gov/content/pkg/FR-2010-05-27/pdf/2010-12646.pdf>.

¹¹ *Id.*

¹² *Id.* at 29,756.

¹³ *Id.*

The TSCA section 14(b) exclusion from confidential protection for information from health and safety studies indicates the importance attributed by Congress to making such information available to the public. Chemical identities in particular constitute basic information that helps the public to place risk information in context. Making public chemical identities in health and safety studies whose confidentiality is precluded by TSCA will support the Agency's mission.¹⁴

This public right to know is even more important where the health and safety information in question is being submitted under section 8(e) of TSCA, which requires companies to immediately report to EPA "information which reasonably supports the conclusion that such substance or mixture presents a substantial risk of injury to health or the environment." 15 U.S.C. § 2607(e).

C. EPA has violated TSCA and its own policy and regulations in approving CBI claims for Substantial Risk Reports.

In light of the above statutory and regulatory requirements and EPA's standing policy, EDF was dismayed to discover that in a number of recent cases EPA has approved chemical identity confidentiality claims in section 8(e) substantial risk notices for chemicals offered for commercial distribution even where those names do not fall under the narrow exceptions TSCA provides for nondisclosure.

Using EPA's most recent posting of its CBI determinations, published on December 9, 2019,¹⁵ we identified a total of 23 section 8(e) submissions in EPA's spreadsheet where EPA has reviewed and approved chemical identity CBI claims. We then sought to examine the specific substantial risk notices by searching for the section 8(e) case numbers in EPA's ChemView database. We were thereby able to locate and inspect the notices for 17 of the 23 cases. (For the other six cases it appears the section 8(e) notices are not available in ChemView.)

For 13 of the 17 cases,¹⁶ EPA approved the CBI claims even though, based on information the submitter provided in the substantiation forms included with the notice, the chemicals in

¹⁴ *Id.* at 29,757.

¹⁵ Final Determination Spreadsheet.

¹⁶ The 13 cases are: 8EHQ-18-21270, 8EHQ-18-21273, 8EHQ-17-20986, 8EHQ-17-20987, 8EHQ-17-20989, 8EHQ-17-20990, 8EHQ-17-20991, 8EHQ-18-21165, 8EHQ-18-21268, 8EHQ-18-21269, 8EHQ-18-21271, 8EHQ-18-21272, and 8EHQ-18-21278. At least 12 and possibly all 13 of these cases involve notices EPA received from one company: JSR Micro/JSR Corporation. In the 13th case (8EHQ-18-21272), it appears EPA may have affixed the wrong cover letter to the notice, as it bears Akzo Nobel's logo, but the notice itself and the accompanying substantiation indicate that JSR was the submitter.

question: a) are being made for uses that fall under TSCA's jurisdiction, b) were previously granted low-volume exemptions (LVEs) by EPA, and c) have been offered for commercial distribution. Nowhere do the submitters indicate that the chemical name falls under TSCA's narrow exception for process or mixture-portionality information. Nor has EPA provided any rationale for its determination, outside of its exceedingly unhelpful boilerplate language: "Submission met the requirements of section 14(c) and substantiation adequately supported all CBI claims." Based on available information, these claims should have been rejected at the outset. To the extent EPA has some rationale, it should be providing it to support its determinations and associated findings.

For the other four cases where we were able to locate the notice in ChemView, we found the following problems:

- 8EHQ-18-21303: All substantiation form entries are redacted and claimed CBI so we were unable to determine whether the claim fell within one of the narrow exceptions for nondisclosure.
- 8EHQ-17-20767: The notice states: "Company name and chemical identity are considered confidential business information (CBI). CBI substantiation is enclosed." However, no substantiation is available in ChemView so we were unable to determine whether the claim fell within one of the narrow exceptions for nondisclosure.
- 8EHQ-18-21466: Lubrizol is identified as the submitter but no substantiation has been included so we were unable to determine whether the claim fell within one of the narrow exceptions for nondisclosure.
- 8EHQ-18-21498: The company name is redacted; the cover letter states the chemical is not on the TSCA Inventory but does not indicate whether it has an exemption; all entries in the substantiation form are redacted; no actual study is included, only a brief summary of the results in the cover letter.

What we have found is deeply disturbing:

- For most of the cases where we could access information, EPA appears to have approved without basis the submitters' CBI claims for chemical identity in their substantial risk notices submitted under TSCA section 8(e).
- In the other cases, EPA has simply not provided the needed substantiation or allowed it to be completely redacted.

EPA's pattern and practice here appears to be in direct violation of TSCA and EPA's regulations, as well as EPA's own policy. With respect to the latter, in no case in its determinations has EPA even mentioned its policy, let alone indicated: whether these cases do not fall under it; if they do not, why not; and if they do, why EPA has failed to abide by its policy.

To be clear, based on available evidence, the policy does apply to these 23 Section 8(e) submissions and EPA should have denied the confidentiality claims for specific chemical identity. If EPA relied on the fact that these chemicals were granted an LVE as a basis for declining to apply the policy (although the policy itself makes no such distinction), it is not legally supportable. For many of these chemicals, the company itself has indicated that these substances have in fact been offered for commercial distribution in the United States. Thus, the CBI claims cannot be exempt under TSCA § 14(c)(2)(G), and as the information involved squarely falls within the definition of TSCA § 14(b)(2)(A)(i), it must be disclosed unless it would disclose process or mixture-portionality information.

In the alternative, on the basis of these comments, EPA now “has a reasonable basis to believe that the information” identified above “does not qualify for protection from disclosure,” and EPA must re-review these claims consistent with TSCA. 15 U.S.C. § 2613(f)(2)(B).

D. EPA appears not to be applying TSCA § 14(b)(2) in its determinations at all.

More broadly, EPA’s determination document does not make clear whether, and if so when, EPA is applying TSCA § 14(b)(2) at all. As far as we can tell, EPA has not denied a *single* confidentiality claim on the basis that the information claimed is a health and safety study, despite TSCA’s clear mandate that such information is generally not eligible for confidentiality. What are the chances that of 609 confidentiality claims approved in full, not a single claim applied to health and safety information? Indeed, as we discuss in detail in section 5 below, numerous CBI claims EPA has approved were asserted for health and safety information submitted to EPA.

On this note, EPA identifies numerous determinations as submission type: “Section 8(e)” and determination type: “All information other than specific chemical identity subject to substantiation requirement.”¹⁷ The summary rationale is then “Submission met the requirements of section 14(c) and substantiation adequately supported all CBI claims.”¹⁸ From these vague summaries, it is impossible to determine what type of information EPA reviewed and why EPA reached the conclusions it did. As noted herein, TSCA § 8(e) notices are health and safety studies that must be disclosed under TSCA § 14(b)(2), so it seems possible if not likely that some of the information claimed here should be disclosed under TSCA § 14(b)(2). But from EPA’s summary and boilerplate analyses, it is completely unclear whether EPA’s review entailed health and safety information and if so, why EPA does not believe that TSCA §14(b)(2) applies, or whether EPA even considered if TSCA §14(b)(2) applies.

¹⁷ *Id.*

¹⁸ *Id.*

EPA must begin applying TSCA § 14(b)(2) and disclosing the health and safety information as required by Congress.

4. EPA lags far behind in reviewing, and where approved, taking required actions for, chemical identity CBI claims under TSCA.

To gain a measure of the extent to which EPA has timely reviewed confidential business information (CBI) claims for chemical identity under TSCA, and taken actions required for any such claims it approves, we examined whether and to what extent EPA has assigned unique identifiers to chemicals for which EPA received Notices of Commencement (NOCs). Since passage of the Lautenberg Act on June 22, 2016, EPA has published in the Federal Register notices of EPA's receipt of NOCs for 678 PMN substances.¹⁹ Of these, 369 PMNs are identified by generic names in the notices of receipt for the NOC, indicating that their specific chemical identities have been claimed CBI by the submitters.

Using EPA's most recent posting of its CBI determinations, published on December 9, 2019,²⁰ we compared this list of 369 NOC'd PMN substances with generic names to the list of chemicals to which EPA has assigned unique identifiers (UIDs) as of December 9, 2019.²¹ Our analysis found that **183 – 49.5%** – of the NOC'd PMN substances with generic names **lack a unique identifier**.

Under TSCA EPA is required to: a) review 100% of CBI claims for chemical identity for chemicals in or entering commerce; b) conduct those reviews within 90 days of receipt of the information bearing the claim; and c) assign a unique identifier to any chemical for which it approves the CBI claim.

¹⁹ EPA's summary statistics on its website, STATISTICS FOR THE NEW CHEMICALS REVIEW PROGRAM UNDER TSCA, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/statistics-new-chemicals-review> (last visited Jan. 24, 2020), indicate it has received 781 NOCs since amended TSCA's passage. However, EPA has only published Federal Register notices for its receipt of NOCs through September of 2019. This time gap likely accounts for the discrepancy in these numbers of NOCs. In addition, our value of 678 NOCs is a unique count; EPA's Federal Register notices may include the same PMN number in the NOCs received table in multiple notices, likely representing EPA's receipt of amended versions of the NOC. In such cases, we have counted each PMN only once, and used as its date of receipt the date indicated in the most recent Federal Register notice listing that PMN number.

²⁰ Final Determination Spreadsheet.

²¹ The same list of UID's assigned as of 12-9-19 appears in two spreadsheets EPA has published. One is on the second tab of CBI REVIEW AND FINAL DETERMINATIONS, https://www.epa.gov/sites/production/files/2019-12/cbi_final_determinations_12-9-19.xlsx. The other is UNIQUE IDENTIFIERS FOR APPROVED TSCA CBI CLAIMS, <https://www.epa.gov/sites/production/files/2019-12/uid-12-9-19.xlsx>. Both files were last visited Jan. 22, 2020.

Because the NOCs we examined were all received prior to October 1, 2019, more than 90 days has elapsed since their receipt. To give EPA the benefit of the doubt given the timing of its release of its CBI determinations on December 9, 2019, we removed any NOCs received in September 2019 from our analysis. That left 363 NOC'd PMN substances with generic names. **Of these, 167 – 46% – lack a unique identifier.**

In sum, EPA failed to timely review chemical identity claims, and assign unique identifiers to the claims it approved, for nearly half of such claims asserted in NOCs received between passage of updated TSCA and the end of September 2019. Given the limited information EPA has provided for other categories of chemical identity CBI claims (*e.g.*, CDR submissions and 8(e) notices), it is far harder to discern what fraction of those claims that should have been reviewed actually have been.

5. Additional EPA CBI Determinations fail to comply with TSCA and EPA's regulations.

During the December 10, 2019, public meeting, EPA pointed to a list of final CBI determinations that EPA published on December 9, 2019, as symbolic of its attempts to implement section 14 of TSCA.²² EDF has a number of legal and factual concerns with these determinations, some of which are also discussed in sections 2, 3, and 4 of these comments. In this section we describe additional problems with some of EPA's determinations.

Over the past two years EDF has requested and received a number of public files for Premanufacturing notices (PMNs) submitted under section 5 of TSCA. EPA has now made and published final CBI determinations for a few of those PMNs. Based on the redactions and substantiations in the public files we received, it is clear that EPA is approving CBI claims that are contrary to section 14 of TSCA and EPA's regulations. EDF and other parties have previously identified and explained some of these legal issues in the Notice of Intent submitted to EPA on September 3, 2019, attached as Appendix A.

Release and exposure information: First, EPA has approved CBI claims for information regarding worker exposures and environmental releases. As discussed in the Notice of Intent (pp. 8-10), this information constitutes health and safety information that cannot be claimed CBI under TSCA. 15 U.S.C. § 2613(b)(2). EPA's regulations make clear that "not only is information which arises as a result of a formal, disciplined study included [in the definition], but other information relating to the effects of a chemical substance or mixture on health or the environment is also included. Any data that bear on the effects of a chemical substance on health

²² CBI REVIEW AND FINAL DETERMINATIONS, https://www.epa.gov/sites/production/files/2019-12/cbi_final_determinations_12-9-19.xlsx (last visited Jan. 14, 2020).

or the environment would be included.” 40 C.F.R. § 720.3(k)(1) (emphasis added). Despite this expansive definition, EPA has approved numerous CBI claims for worker exposure and environmental release information, as detailed below by PMN number.

Safety data sheets: Second, based on the contents of the public files we received, EPA has also unlawfully approved CBI claims for safety data sheets (SDSs). EPA has a nondiscretionary duty to include in the public files safety data sheets submitted with a PMN because safety data sheets: (1) do not meet the requirements for confidentiality established in § 2613(c)(1)(B); and (2) contain information from health and safety studies that cannot be withheld as confidential. See our Notice of Intent for further discussion of these requirements.²³ Despite this nondiscretionary duty, EPA repeatedly approved CBI claims for entire SDSs, as detailed below by PMN number.

Missing substantiation documents: Lastly, for a number of public files we received containing CBI claims that EPA has subsequently approved, the public file did not contain a substantiation document. As explained in the Notice of Intent (p. 12):

A PMN submitter who claims that a PMN or supporting information contains confidential information that is protected from disclosure under TSCA must generally substantiate that claim by contemporaneously submitting certain information to EPA. 15 U.S.C. § 2613(c)(3); 40 C.F.R. § 2.204(e) (describing the information that must be submitted); 82 Fed. Reg. 6522, 6522 (Jan. 19, 2017) (“EPA has determined that [15 U.S.C. § 2613(c)(3)] requires an affected business to substantiate all TSCA CBI claims *** at the time the affected business submits the claimed information to EPA.”). If the PMN submitter claims that information in this substantiation document is itself protected as confidential under § 2613, the PMN submitter must provide “a sanitized copy” of the substantiation document, which EPA must place in the public file. 40 C.F.R. § 720.80(b)(2).

While certain categories of information are exempted from the substantiation requirement, see 15 U.S.C. § 2613(c)(2), the PMNs listed below that did not include substantiation forms asserted CBI claims for types of information that clearly do not fall within the section 14(c)(2) exemptions, e.g., worker release information, environmental release information, and SDSs.

Examples of unlawful approvals of CBI claims in PMNs: For the following PMNs, EPA’s Final Determination spreadsheet indicated that EPA approved all CBI claims made by the submitter. In each case we discuss CBI claims that should not have been allowed to be asserted and certainly should not have been approved.

²³ Earthjustice, et al., Notice of Intent to Sue EPA p. 11 (Sept. 3, 2019), <https://www.epa.gov/sites/production/files/2019-09/documents/noi.pdf>.

P-16-0512:

EPA's PMN form includes a section on environmental release information. For this PMN, the information in this section that was redacted includes:

- An “[e]stimate [for] the amount of the new substance released (a) directly to the environment or (b) into control technology to the environment (in kg/day or kg/batch).” (PMN p. 16);
- A description of the “media of release i.e. stack air, fugitive air (optional-see Instructions Manual), surface water, on-site or off-site land or incineration, POTW, or other (specify) and control technology, if any, that will be used to limit the release of the new substance to the environment.” (PMN p. 16).

As discussed above, EPA's regulations make clear that these types of information constitute health and safety information, which cannot be claimed CBI under TSCA.

Also, despite these redactions, the public file did not contain a substantiation document.

P-19-0030:

The submitter redacted worker exposure-related information in the PMN, including the protective equipment/engineering controls that would be used by the workers (PMN p. 15).

The submitter also redacted the amount of the substance that would be released to the environment, and whether it would be released to the air, water, or land (PMN p. 16).

Lastly, despite the redactions, the public file did not contain a substantiation document.

P-19-0040:

The public file for P-19-0040 included an SDS that consisted of only a single, entirely blank page. According to the List of Attachments in the PMN, this SDS is an eight-page document. As discussed above, SDSs contain health and safety information that cannot be claimed CBI.

The submitter also included an optional pollution prevention form that was completely redacted, provided as a single-page, entirely blank document. The PMN identifies this as a 14-page document. According to EPA, this type of form is intended for “the submitter [to] provide information regarding its efforts to reduce or minimize pollution associated with activities

surrounding manufacturing, processing, use, and disposal of the PMN substance.”²⁴ As discussed above, this type of information falls squarely within the definition of health and safety information.

P-19-0092:

The List of Attachments at the end of the PMN form states that a six-page SDS was included in the submission; however, EPA did not provide an SDS in the public file. Although it is not clear from the substantiation form whether the submitter intended to claim the entire SDS as CBI, EPA should not have approved this CBI claim.

Additionally, all worker exposure-related activity described in the PMN was claimed CBI. At a minimum, the information in the PMN Form that directly relates to exposures to workers (*e.g.*, the duration and frequency of exposures) constitutes health and safety information that must be disclosed unless it falls under the narrow exception under TSCA section 14(b)(2) for process information. And EPA should not simply rely on submitters’ assertions that disclosure of certain information will disclose process information; EPA needs a real factual basis for concluding that disclosure of the information will disclose process information.

* * *

With respect to the health and safety information subject to TSCA § 14(b)(2) described above, EPA should have rejected the confidentiality claims outright and should now do so in all of the cases discussed in this section. In the alternative, because, on the basis of these comments, EPA now “has a reasonable basis to believe that th[is] information does not qualify for protection from disclosure” EPA must re-review these claims consistent with TSCA. 15 U.S.C. § 2613(f)(2)(B). Moreover, as EPA continues to review CBI claims, EPA must ensure that its CBI determinations are consistent with TSCA and EPA’s regulations.

6. EPA has not posted a number of PMNs to ChemView that were received well after it said it would do so.

As of January 24, 2020, EPA has posted 139 PMNs to ChemView. EPA began posting PMNs to ChemView on May 30 or 31, 2019. On May 20 and again on May 28, 2019, EPA posted to its OPPT listserv notices titled “Alert to TSCA Section 5 Submitters: Imminent Changes in Public Availability of Your Submissions” that stated (emphasis in original):

²⁴ U.S. EPA, *Chemistry Assistance Manual for Premanufacture Notification Submitters* p. 97-98 (Mar. 1997), https://www.epa.gov/sites/production/files/2014-05/documents/chemistry_assistance_manual_for_premanufacture_notification_submitters_0.pdf.

Starting May 30, 2019, EPA will begin publishing TSCA Section 5 (PMN, MCAN and SNUN) notices, their attachments, including any health and safety studies, any modifications thereto, and all other associated information in ChemView – *in the form they are received by EPA*. EPA will not be reviewing CBI-sanitized filings before publishing.

In addition, EPA’s webpage for ChemView²⁵ states (emphasis in original):

What’s new in ChemView?

May 31, 2019 – As part of EPA's efforts to increase transparency, the Agency is working to provide the public with close to real-time, electronic access to industry pre-manufacture notices for new chemicals, including health and safety studies and other information relevant to EPA’s safety review. This step is one of EPA’s commitments to enhance transparency and provide the public with information on new chemicals as part of the Agency’s implementation of the Lautenberg Chemical Safety Act.

On May 31st, EPA posted six Pre-Manufacture Notices (PMNs) and associated attachments into ChemView, EPA’s electronic chemicals database. EPA chose these six cases because they were submitted recently, and they will serve as examples of what is to become routine practice. Moving forward, EPA will make TSCA Section 5 (PMN, MCAN and SNUN) notices, their attachments, including any health and safety studies, any modifications thereto, and all other associated information publicly available in ChemView within 45 days of their receipt – *in the form they are received by EPA*. EPA will not be reviewing CBI-sanitized filings before publishing.

EDF compared the list of PMNs posted to ChemView with the list of PMNs received that EPA has posted to its “status table” that tracks receipt and review of PMNs.²⁶ We first identified all PMNs with received dates after May 31, 2019, and then eliminated those with an interim status designation of “Invalid.” This process identified 130 valid PMNs received by EPA after May 31, 2019.

Comparing the two lists, we identified eight PMNs that should have been posted to ChemView but have not been as of January 24, 2020:

²⁵ INTRODUCTION TO CHEMVIEW, <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/introduction-chemview#new> (last visited Jan. 24, 2020).

²⁶ PREMANUFACTURE NOTICES (PMNS) AND SIGNIFICANT NEW USE NOTICES (SNUNS) TABLE, <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/premanufacture-notices-pmns-and> (last visited Jan. 24, 2020).

PMN Number	Received Date	Interim Status	Focus Meeting Date	Final Disposition	Effective Date
P-20-0040	1/6/2020				
P-18-0350	12/4/2019				
P-20-0009	10/21/2019	Scoping Meeting Occurred	11/7/2019		
P-19-0141	9/19/2019	Scoping Meeting Occurred	10/10/2019		
P-19-0162	9/11/2019	Scoping Meeting Occurred	10/3/2019		
P-19-0135	9/6/2019	Scoping Meeting Occurred	10/1/2019	'Not likely to present an unreasonable risk' section 5(a)(3)(C) determination	12/18/2019
P-19-0047	7/31/2019	Scoping Meeting Occurred	8/22/2019	'Not likely to present an unreasonable risk' section 5(a)(3)(C) determination	8/29/2019
P-18-0295	6/17/2019	Scoping Meeting Occurred	7/11/2019	'Not likely to present an unreasonable risk' section 5(a)(3)(C) determination	9/30/2019

While one of these PMNs was only recently received, five other PMNs that were received the same day or later are posted to ChemView. And the remaining seven PMNs not available on ChemView were all received over a month ago.

Of particular concern is that three of the PMNs not available through ChemView have already received “not likely” determinations – meaning that the public had no access to the PMNs or associated documents during the review period, and even now that the chemicals have been greenlighted to enter commerce, the public *still* lacks access to any of that information.

A possible clue as to why the PMNs have not been posted emerges from our separate effort to gain access to three of these PMNs. On October 18, 2019, EDF requested the public file for two of these chemicals with “not likely” determinations.²⁷ EPA’s response to those requests (received by EDF on December 12, 2019) was that the public files could not yet be provided to us due to “CBI” issues. As of today (January 24, 2020), EDF still has not received the public files for these two PMNs.

EPA’s citing of “CBI issues” as the basis for its delay in providing public access to the requested information is highly problematic, as it flies in the face of EPA’s own repeated statements (quoted above) that it would promptly post PMNs to ChemView “*in the form they are received by EPA*” (emphasis in original). What possible “CBI issues” would preclude EPA providing EDF with the public files or posting them in ChemView, given that EPA has given submitters ample advance notice of its intent to post the PMNs in the form in which they are received. If

²⁷ We have separately requested the public file for the third PMN, but have not yet received a response from EPA.

companies are failing to redact information they wanted to hide from the public, that is no basis for EPA to deny the public timely access to these PMNs.

7. Recommended modifications to ChemView and EPA's websites on new chemicals.

Although EPA has made a number of useful modifications to its websites that contain information on new chemicals, there are still serious limitations to the functionality of those websites. EDF is providing a number of recommendations for additional modifications that would enhance utility.

New chemical notices posted on Chemview

- Where a PMN substance also has a CAS number, searching ChemView using either number needs to bring up the new chemical notice for the substance. Currently in such cases, ChemView retrieves the notice only if one somehow knows and searches using the CAS number and does not “crosswalk” that CAS number to the PMN number. A recent example is PMN P-20-0025, which has the CAS number 61800-40-6. Searching for the PMN number in ChemView yields no match, while searching for the CAS number does find it.
 - This is problematic because among other things the Federal Register notices (and the new website with PMN tables corresponding to the notices, as well as the status table), do not use or include CAS numbers. For such chemicals there is no straightforward way to know a CAS number exists for the substance, which means the public cannot rely on the identifiers used in PMN and status table entries to reliably search for their corresponding ChemView postings.
 - At the very least ChemView should allow those entries to be found by searching for either PMN or CAS number. Ideally, the results displayed in ChemView would list both the PMN number and (where available) the CAS number.
- In addition, the export file that lists the PMNs posted to ChemView currently lists this type of PMN only using its CAS number and not its PMN number. One has to click into the specific submission to find the PMN number associated with that CAS number. The export file should have separate columns for PMN number and (where applicable) CAS number.
- The list of the new chemical notices posted in ChemView lacks a date field that would allow the user to know when a posting is first posted or most recently updated. There are currently 145 PMNs, SNUNs, and MCANs posted. The only way to determine if EPA has posted a new version is by clicking through all 145 entries one at a time to look for new versions.
 - An easy solution is to have a date field in the list of PMNs, SNUNs, and MCANs posted in Chemview that is generated by selecting “New Chemical Notices” under “Information Submitted to EPA” and pressing “Generate results.” The date field would indicate when a new chemical notice was posted or last updated, and

would be included in the export file. That way, users could look for dates since the last time they checked and know which entries have been added or updated.

- The spreadsheet that can be exported for new chemical notices currently provides very little useful information. It should contain all of the information that EPA already summarizes in the pop-up windows for each new chemical notice.

EPA's new chemical website tables

- An export function to Excel for the entries in all such tables should be provided. Copying from html-based websites into Excel results in numerous formatting problems and errors.
- The functionality to show “all” entries should be used for all of these tables. Currently it has been applied to the tables for notices of PMN receipts; the status table; and the “not likely” determination table, but is missing from the tables for notices of receipt for NOCs and test data.
- The outputs from ChemView itself when selecting “Generate results” can currently be displayed for 10, 25, 50 or 100 entries. The functionality to show all entries should also be added to ChemView.

EPA's posting of consent orders in ChemView and on status table

- EPA is very delayed in posting consent orders to ChemView. Some consent orders with effective dates as far back as June 2019 are still not publicly available. In many cases, even when EPA updates the status table to indicate that a consent order has been finalized, months will pass before the consent order is made available in Chemview or via a link from the status table.
- EPA's status table states: “Please note: Links to consent orders are generally available within two weeks of the order's effective date.” This has not been the case for some time. EPA should ensure that consent orders are made publicly available in a timely manner.

EPA's Section 8(e) notices in ChemView

- The number of such notices and ability to access them differs radically, depending on how one searches ChemView:
 - If one only selects the “Substantial risk reports” option under “Show Output Selection” in the main ChemView page (i.e., the “Chemical” tab), 3,901 entries are shown.
 - If one does the exact same search but on the “Advanced Search” tab, 17,378 entries are shown on the Chemicals tab, but only 53 entries are shown on the “Cases” tab.
 - If one uses the Advanced Search tab, enters “starts with 8EHQ” in the “Document Information” section, and selects the “Substantial risk reports” option under

“Show Output Selection,” Chemview shows 12,686 entries on the Chemicals tab, but only 51 entries are shown on the “Cases” tab.

- As a result, it is not at all clear how many and which section 8(e) notices are accessible in ChemView.
- The retrieved records not only vary but are variously identified by different identifiers, some by CAS number, others by PMN number, others by section 8(e) notice numbers – with no way to crosswalk between these identifiers. It should be possible to search for all applicable identifiers, view all relevant records in Chemview, and view all identifiers in the export file in separate columns.

ChemView export files

- In general, the export files should include all of the information that appears in the pop-up window summaries EPA has developed. As of now they only include a few links that are not particularly helpful.
- There appears to be no way currently to capture the content of those pop-up windows, which would be very useful content both on individual substances and for a group of substances for further analysis.
- EPA has clearly devoted considerable time and effort to developing and populating these pop-up windows, using a standard format that could and should be readily mapped into the corresponding export files, with the sections/headers in the pop-up window becoming column or row headers in the export file. This would allow information on multiple substances or actions to be captured in a form amenable to further analysis.

Need to add date fields to the entries in all tables and export files

- Currently it is difficult if not impossible to know what has been added to or modified in a table or export file between one viewing and the next. While EPA has in a few places indicated when a page or table as a whole has been updated, this is of limited utility because it still requires the user to engage in a tedious process to determine exactly which records or entries are newly added and which existing entries have been modified.
- EPA needs to include a field in each record/entry that lists the “date added/last modified.” The sorting or filtering by that field can allow ready identification of the specific changes EPA has made since the user last viewed the information.

* * * * *

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