Environmental Defense Fund Comments on

Guidance on Expanded Access to TSCA Confidential Business Information

Docket ID: EPA-HQ-OPPT-2017-0652

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Environmental Defense Fund (EDF) appreciates the opportunity to provide comments to the Environmental Protection Agency (EPA) on EPA's draft guidance documents for each of three new expanded confidential business information (CBI) access provisions under the Toxic Substances Control Act (TSCA), as amended by the Lautenberg Act enacted in 2016. 83 Fed. Reg. 11,748 (March 16, 2018).

EDF first provides a legal and factual background, followed by comments on issues applicable to all three draft guidance documents, and then more specific comments on the draft guidance for access by:

- state, local, and tribal governments (hereinafter "SLT guidance")[1],
- medical and environmental professionals in non-emergency situations (hereinafter "NEM guidance")[2], and
- certain persons in emergency situations (hereinafter "EM guidance")[3].

[1] EPA, A DRAFT guide for access to TSCA CBI for state, local, and tribal governments (March 12, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-0007.

[2] EPA, A DRAFT guide for access to TSCA CBI for medical and environmental professionals in non-emergency situations (March 12, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-0004.

[3] EPA, A DRAFT guide for access to TSCA CBI in emergency situations (March 12, 2018), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2017-0652-0005.

Contents:

I. Legal & Factual Background

As explained more below, EPA's draft guidance documents fail to characterize TSCA § 14's provisions accurately. Because EPA's documents reflect consistent confusion about the requirements of TSCA § 14 as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (Lautenberg Act), we begin our comments by reviewing the history of those amendments and the text of the amended law.

A. EPA has long failed to review confidentiality claims, and many confidentiality claims lack merit.

Numerous government-sponsored studies of EPA's management of confidentiality claims under TSCA have found that EPA systematically failed to scrutinize claims and that many claims, once scrutinized, lacked merit. *See, e.g.*, Hampshire Research Associations, Inc., Influence of CBI Requirements on TSCA Implementation (March 1992), https://www.regulations.gov/document?D=EPA-HQ-OPPT-2002-0054-0074. For example, the Hampshire study found that, when substantially identical information was submitted under TSCA and another federal statute, the Emergency Planning and Community Right-to-Know Act (EPCRA), the confidentiality claim rate under TSCA was at least 10 times higher than the rate under EPCRA; more probably, the claim rate was "more than a thousand times higher under TSCA." *Id.* at 41. In addition, in those cases where EPA expended the resources to review claims, EPA found up to 50% to be invalid. When submitters of these claims were challenged, EPA prevailed in every case. *Id.*

EPA has made limited progress in addressing these issues. In 2005, the Government Accountability Office (GAO) reported that "[t]he EPA official responsible for initiating challenges to confidentiality claims told [GAO] that EPA challenges about 14 such claims each year, and that the chemical companies withdraw nearly all of the claims challenged." GAO, Chemical Regulation, Options Exist to Improve EPA's Ability to Assess Health Risks and Manage its Chemical Review Program 33 (June 2005), https://www.gao.gov/assets/250/246667.pdf.

B. The Lautenberg Act substantially revised the confidentiality requirements of TSCA § 14.

The Lautenberg Act substantially revised TSCA § 14, 15 U.S.C. § 2613, which governs the disclosure of information covered by Freedom of Information Act (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). TSCA § 14, in turn, provides that, "[e]xcept as provided in this section, [EPA] shall not disclose information that is exempt from disclosure pursuant to [Exemption 4]—(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. To refuse to disclose information, EPA first has to establish that information falls within FOIA Exemption 4. *In addition*, EPA has to determine that the information meets the requirements of TSCA § 14(c).

In turn, TSCA § 14(c) provides additional requirements for confidentiality, creating a three-step procedure for assertion, substantiation, and review of a claim for protection from disclosure. At the first

step, a person must assert the claim and make a statement supporting the claim "concurrent with submission of the information" to which the claim applies. 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;
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> (ii) determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
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> (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).

The second procedural step is substantiation. TSCA § 14(c)(2) exempts certain information from the substantiation requirements. *See id.* § 2613(c)(2). For all other information, "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim." Id. § 2613(c)(3). EPA has recognized that the substantiation requirement is not conditional upon a future rulemaking. 82 Fed. Reg. 6522, 6523 (Jan. 19, 2017).

At the third procedural step, EPA must review certain claims and make a determination on the claims within 90 days. EPA must review "all" CBI claims for specific chemical identities (with one exception). 15 U.S.C. § 2613(g)(1)(C)(i). EPA must also "review a representative subset, comprising at least 25 percent, of all other claims or requests for protection from disclosure under this section." *Id.* § 2613(g)(1)(C)(ii). Section 14 imposes strict deadlines on this process. For new CBI claims asserted after the passage of the Lautenberg Act, except for those under (c)(2), EPA must "not later than 90 days after the receipt of a claim" "review and approve, approve in part and deny in part, or deny the claim or request." *Id.* § 2613(g)(1)(A). If EPA denies all or part of the claim, EPA must notify the claimant, who then has a short time period to file a lawsuit against EPA challenging disclosure. *Id.* § 2613(g)(2)(A), (D). Under TSCA § 26(j), EPA must make its confidentiality determinations available to the public. *Id.* § 2625(j)(1).

C. TSCA § 14(d) requires EPA to disclose confidential information to, among others, three additional categories of people.

TSCA § 14(d) applies to all confidential information under TSCA § 14. 15 U.S.C. § 2613(d). Three of its provisions are at issue here, and each *mandates* that EPA share confidential information with the categories of people described, subject to certain conditions. *See, e.g.*, *id.* § 2613(d)(4) ("Information described in subsection (a) *** *shall* be disclosed to a State, political subdivision of a State, or tribal government ***") (emphasis added); § 2613(d)(5) ("Information described in subsection (a) *** shall be disclosed to a health or environmental professional ***"); § 2613(d)(6) ("Information described in

subsection (a) *** shall be disclosed in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder ***").

First, TSCA § 14(d)(4) requires that EPA "shall" disclose confidential information "to a State, political subdivision of a State, or tribal government, on written request, for the purpose of administration or enforcement of a law if such entity has 1 or more applicable agreements with [EPA]." 15 U.S.C. § 2613(d)(4). The applicable agreement should be "consistent with the guidance developed under subsection (c)(4)(B) and ensure that the entity will take appropriate measures, and has adequate authority, to maintain the confidentiality of the information in accordance with procedures comparable to the procedures used by [EPA] to safeguard the information." *Id.* As relevant here, TSCA § 14(c)(4)(B) provides that EPA shall "develop guidance regarding *** the content and form of the *** agreements required under paragraph[] (4)." *Id.* § 2613(c)(4)(B). Thus, for a state, political subdivision of a state, or tribal government to obtain confidential information, TSCA § 14(d)(4) substantively requires that the entity "take appropriate measures" and have "adequate authority" to maintain confidentiality "in accordance with procedures comparable to the procedures used by [EPA] to safeguard the information." *Id.* § 2613(d)(4).

Second, TSCA § 14(d)(5) requires that EPA "shall" disclose confidential information "to a health or environmental professional employed by a Federal or State agency or tribal government or a treating physician or nurse in a nonemergency situation if such person provides a written statement of need and agrees to sign a written confidentiality agreement with [EPA]," subject to certain conditions. 15 U.S.C. § 2613(d)(5). The statement of need and confidentiality agreement should be consistent with the content and form of the guidance developed by EPA under TSCA § 14(c)(4)(B). *Id.* § 2613(d)(5)(A). Substantively, the statement of need shall state:

> [T]hat the person has a reasonable basis to suspect that—
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> (i) the information is necessary for, or will assist in—
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> (I) the diagnosis or treatment of 1 or more individuals; or
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> (II) responding to an environmental release or exposure; and
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> (ii) 1 or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned, or an environmental release of or exposure to the chemical substance or mixture concerned has occurred; and
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> (C) the person will not use the information for any purpose other than the health or environmental needs asserted in the statement of need, except as otherwise may be authorized by the terms of the agreement or by the person who has a claim under this section with respect to the information;

Id. § 2613(d)(5)(B)-(C).

Third, TSCA § 14(d)(6) requires that EPA "shall" disclose confidential information "in the event of an emergency to a treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a State, or tribal government, or first responder *** if such person requests the information," subject to certain conditions. 15 U.S.C. § 2613(d)(6). "[F]irst responder" is defined broadly to include (but not be limited to) "any individual duly authorized by a Federal agency, State, political subdivision of a State, or tribal government who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician." *Id.* To obtain this information, substantively, a person must

> have a reasonable basis to suspect that—
>
> (i) a medical, public health, or environmental emergency exists;
>
> (ii) the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or
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> (iii) 1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred.

15 U.S.C. § 2613(d)(6)(A). Procedurally, to obtain the information, "if requested by a person who has a claim with respect to the information under this section," the person should "provide a written statement of need and agree to sign a confidentiality agreement" as required for health and environmental professionals and others under TSCA § 14(d)(5), described above. *Id.* § 2613(d)(6)(B)(i). TSCA § 14(d)(6) provides that the person should "submit to [EPA] such statement of need and confidentiality agreement as soon as practicable, but not necessarily before the information is disclosed." *Id.* § 2613(d)(6)(B)(ii).

To implement TSCA § 14(d)(5) and (d)(6), EPA has an affirmative duty to, in consultation with the Centers for Disease Control and Prevention (CDC), "develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d)." 15 U.S.C. § 2613(g)(3).

When EPA shares confidential information under TSCA § 14(d)(4)-(6), TSCA § 14 creates specific and limited rights for the persons who originally provided that information and claimed it confidential (hereinafter, confidentiality claimants). First, when EPA "intends to disclose information pursuant to subsection (d)," EPA "shall notify, in writing, the person that asserted the claim *** of the intent of [EPA] to disclose the information or not protect the information from disclosure under this section." 15 U.S.C. § 2613(g)(2)(A). "For information [EPA] intends to disclose under" § 14(d)(4) and 14(d)(5), "[EPA] shall not disclose the information until the date that is 15 days after the date on which the person that asserted the claim *** receives notification." *Id.* § 2613(g)(2)(C)(i). With respect to information disclosed under § 14(d)(6), EPA "shall notify the person that submitted the information that the information has been disclosed as soon as practicable after disclosure of the information." *Id.* § 2613(g)(2)(C)(ii).

Second, if a confidentiality claimant receives notification and "believes the information is protected from disclosure under this section, before the date on which the information is to be disclosed pursuant to subparagraph *** (C) the person may bring an action to restrain disclosure of the information in" federal district court. *Id.* § 2613(g)(2)(D)(i). EPA generally shall not disclose information subject to such a challenge before the court rules, *except* EPA *shall* disclose information under TSCA § 14(d)(4). *Id.* § 2613(g)(2)(D)(ii).

COMMENTS ON ISSUES APPLICABLE TO ALL THREE DRAFT GUIDANCE DOCUMENTS

II. The disclosure requirements of TSCA § 14(d)(4)-(6) are mandatory, not discretionary.

EPA's Federal Register Notice, some of the Guidance documents, EPA's website on CBI access,[4] and the related ICR inaccurately imply the disclosure provisions of TSCA § 14(d)(4)-(6) are discretionary. For example, in the Federal Register notice, EPA states that "EPA *may* disclose" confidential information under these provisions. 83 Fed. Reg. 11,748, 11,749 (March 16, 2018) (emphasis added). In the Prefaces of each of the Guidance documents, EPA states that these provisions "authorize[] disclosure." *See, e.g.*, SLT guidance p.2.

In fact, EPA *must* disclose confidential information to people who meet the requirements of TSCA § 14(d)(4)-(6). Each of these provisions uses the mandatory "shall" and expressly requires disclosure. For example, TSCA § 14(d)(4) states that confidential information "*shall* be disclosed to a State, political subdivision of a State, or tribal government" meeting the requirements of (d)(4). 15 U.S.C. § 2613(d)(4) (emphasis added); *see also* 15 U.S.C. § 2613(d)(5), (d)(6). The use of the phrase "shall be disclosed" leaves EPA no discretion to refuse to disclose information if the person meets the criteria of these provisions. *See Sierra Club v. Johnson*, 541 F.3d 1257, 1265 (11th Cir. 2008) ("Congress's use of the word 'shall' creates a nondiscretionary duty for [EPA]."). This is particularly so because TSCA § 14(d)(7) uses the discretionary language of "may," stating that confidential information "may be disclosed if [EPA] determines that ***." 15 U.S.C. § 2613(d)(7).[5] "[Where] Congress includes particular language in one section of a statute but omits it in another section of the same Act, it is generally presumed that Congress acts intentionally and purposely in the disparate inclusion or exclusion." *Russello v. United States*, 464 U.S. 16, 23 (1983) (quoting *United States v. Wong Kim Bo*, 472 F.2d 720, 722 (5th Cir. 1972).

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[4] EPA's website on CBI access declares, for instance, that: "TSCA allows EPA, under certain conditions and when there is a need, to disclose CBI to:

- state, tribal, and local governments;
- environmental, health, and medical professionals; and
- emergency responders."

REQUESTING ACCESS TO CBI UNDER TSCA, https://www.epa.gov/tsca-cbi/requesting-access-cbi-under-tsca (last visited Apr. 13, 2018).

[5] Looking to TSCA § 14(d) as a whole, Congress expressly created eight situations where EPA *must* disclose confidential information, beginning each provision with the requirement that confidential information "shall be disclosed." 15 U.S.C. § 2613(d)(1)-(6), (8)-(9). Congress included only a single discretionary disclosure provision in § 14(d), TSCA § 14(d)(7). 15 U.S.C. § 2613(d)(7).

Here, Congress chose to make the disclosure requirements of TSCA § 14(d)(4)-(6) mandatory and used the language of "shall," in contrast to the discretionary "may" used in the neighboring provision of TSCA § 14(d)(7). S. Rep. 114-67, at 23 (June 18, 2015) (stating that these provisions "remedy a deficiency" in old TSCA by "*ensur[ing]* that treating physicians, nurses, agents of poison control centers, public health or environmental officials of a State or political subdivision of a State, and first responders have appropriate, timely access to information, while still protecting CBI from disclosures more broadly") (emphasis added).

In each place EPA describes access to CBI, including the guidance documents and EPA's website, EPA must acknowledge that it has a mandatory duty to disclose confidential information to persons meeting the requirements of TSCA § 14(d)(4)-(6). Acknowledging this duty will ensure that EPA honors the duty (as it must), and it will encourage persons who qualify to receive confidential information to seek it, knowing that they will receive the information if they meet the requirements.

III. EPA should use language that better reflects that these are guidance documents that do not create binding requirements.

At the outset of the guidance documents, EPA states that these guidance documents are not rulemaking and that "[n]on-mandatory language such as 'should' provides recommendations and does not impose any legally binding requirements." SLT guidance p.1; NEM guidance p.1; EM guidance p.1. But EPA needs to consistently choose language that reflects that understanding, so that EPA actually applies these documents as guidance documents and not as binding requirements. In modern English, the word "should" generally indicates obligation, duty, and correctness. *See Oxford American Dictionary* 1617 (3d ed. 2010). Often it is not the appropriate word for guidance, and EPA should consider "may" or alternative words when appropriate.

Congress directed EPA to develop "guidance" documents for TSCA § 14(d)(4)-(6). 15 U.S.C. § 2613(c)(4)(B). EPA has reasonably chosen to interpret that mandate as requiring *nonbinding* guidance, as reflected by disclaimers at the outset of these documents. Notably, Congress required EPA to promulgate various binding rules in the Lautenberg Act, *see, e.g.*, 15 U.S.C. § 2605(b)(1)(A), and Congress selectively chose *not* to require rulemaking here. Thus, Congress clearly contemplated that these documents would not be binding requirements but true guidance. EPA should honor that intent.

To honor that intent, disclaimers alone are insufficient. EPA cannot rely on those disclaimers to try to avoid judicial review if the documents are riddled with the language of instruction and binding requirements. The D.C. Circuit has expressly rejected the position that a disclaimer renders a guidance document unreviewable; after all, such a disclaimer can be mere "boilerplate." *Appalachian Power Co. v. EPA*, 208 F.3d 1015, 1023 (D.C. Cir. 2000). Guidance should not be written with the language of a rule. Unlike a rule, guidance should not command, require, order, or dictate. *See id.* Guidance is not binding, and the language should reflect that fact.

Here, EPA needs to change some of the language to more clearly reflect that these documents are merely guidance and are truly non-binding. For example, EPA often needs to replace the word "should" with "may" or similarly qualified language.

Of course, where EPA is citing mandatory provisions that are in the statute, it should accurately describe those provisions as mandatory (as, for example, we described in Part II of these comments).

IV. EPA needs to fix its approach to claimed CBI by choosing accurate language.

A. EPA's definition of "TSCA CBI" inaccurately conflates claims for CBI as the equivalent to CBI; EDF suggests that EPA select a different phrase or term to describe this category of information.

i) *EPA is actually describing information that is claimed to be CBI, not necessarily CBI information.*

In all three guidance documents, EPA adopts a definition of "TSCA Confidential Business Information (TSCA CBI)" which is inaccurate and introduces confusion. Specifically, all three define this phrase as meaning: "information submitted to EPA under TSCA, *for which a business has made a claim* of business confidentiality *that EPA has not denied*, that has not otherwise expired, or that the business has not waived or withdrawn." SLT guidance p.5; NEM guidance p.4; EM guidance p.5 (emphases added). This definition is inaccurate because "information submitted to EPA under TSCA, for which a business has made a claim of business confidentiality that EPA has not denied," is *not* necessarily TSCA CBI. As explained in Part I.A, ample factual evidence establishes that persons often *claim* that certain information merits confidential protection under TSCA even when the information does not meet the requirements for confidentiality under TSCA § 14. And if the information does not meet the requirements for confidentiality under TSCA § 14, it does not constitute "TSCA CBI."

Indeed, Congress has imposed a duty on EPA to review many CBI claims within 90 days of receipt and to deny those that do not meet the requirements of TSCA § 14. 15 U.S.C. § 2613(g)(1)(A). This and other provisions of the statute make it clear that a claim, standing alone, is not sufficient to mean information merits confidential treatment. Of course, as a practical matter, EPA protects such information until the claim has been reviewed, and due to resource constraints, Congress has required EPA to review only a subset of most types of claims. *See, e.g.*, *id.* § 2613(g)(1)(C). But EPA should not identify such information as meeting the requirements for confidentiality under TSCA § 14 when EPA has not yet reviewed the claim.

Nonetheless, EDF recognizes that EPA has some sound reasons for wanting an expansive term that covers *both* truly confidential information and information that is merely claimed CBI but not yet reviewed. EPA correctly recognizes that it must share information claimed confidential with the persons identified in TSCA § 14(d)(4)-(6), even if the confidentiality claim has not yet been reviewed by EPA. Textually, TSCA § 14(d)(4)-(6) require the disclosure of the information claimed confidential, regardless of whether the claim has been reviewed. And, of course, in those circumstances where the claim is invalid, EPA should be revealing the information to the public at large. So logically, it would be arbitrary to withhold information from persons identified in TSCA § 14(d)(4)-(6) because claims have not yet been reviewed; regardless of the outcome of the review, the information should be shared with such persons, subject to certain conditions. In addition, it would be irrational for EPA to *presume* information meets the requirements of § 14(a), and therefore withhold it from the public, and then turn around and

presume it does not meet § 14(a) and then refuse to share to persons under TSCA § 14(d)(4)-(6). EPA has to be consistent.

EDF recommends that EPA address this inaccuracy by using a term other than "TSCA CBI." "Claimed TSCA CBI" would be one alternative. After all, EPA is sweeping broadly to encompass all information that has been claimed CBI. Information that has been reviewed and found to meet the requirements of subsection (c) is arguably still "Claimed TSCA CBI." And information arguably no longer falls within this category when the claim fails or ceases to exist for some reason. For example, such information arguably ceases to be claimed TSCA CBI once EPA denies the claim, or the claim expires, or the claim has been waived or withdrawn. Of course, in those circumstances, EPA should be making the information broadly available to the public at large, including all persons identified in TSCA § 14(d)(4)-(6).

For these reasons, EPA should adopt a different term to describe the universe of information it plans to share under the guidance documents. EPA has correctly recognized that it must share all confidential information *and* all information subject to un-reviewed confidentiality claims in accordance with TSCA § 14(d)(4)-(6), and EPA should adopt terminology that reflects that understanding while not imparting true CBI status on information that has merely been claimed CBI.

ii) *EPA inaccurately suggests that health and safety information is CBI.*

The above problem with terminology results in EPA making imprecise statements about health and safety information. For example, in the guidance document governing disclosure to states and other governments, EPA asks the requester to list any laws, policy, or procedures that require disclosure of "TSCA CBI" and EPA provides the example of "health and safety data" as information that EPA must disclose. SLT guidance p.10; *see also* NEM guidance p.8 (suggesting that health and safety data is appropriately CBI); EM guidance p.10 (same). EPA is correct that EPA has a mandatory obligation to release health and safety data. TSCA specifies that such "[i]nformation [is] not protected from disclosure." *Id.* § 2613(b)(2). *But* that information is *not* TSCA CBI. By definition, TSCA excludes such information from the confidentiality provisions of TSCA. *Id.* To be precise, this information is not confidential information *at all*, whereas EPA imprecisely suggests that it is confidential information that EPA must disclose.

To be sure, despite the fact that TSCA is clear that health and safety information (subject to very narrow exceptions) is not eligible for protection from disclosure, persons sometimes *claim* health and safety data merits confidentiality, and it is crucially important that EPA share such information with persons identified in TSCA § 14(d)(4)-(6) even if EPA has not yet reviewed (and denied) the claim. But this example highlights that EPA needs to adopt a more precise term to describe the universe of information EPA plans to share under TSCA § 14(d)(4)-(6). EPA plans to share all information subject to a confidentiality claim, even if the confidentiality claim is not allowed or is invalid.

In addition, if EPA finds that a person has claimed information that clearly does not qualify for protection from disclosure pursuant to TSCA § 14(b), then EPA should review *all* of the CBI claims submitted by that claimant. In such a circumstance, EPA has knowledge that the person is not following the laws governing CBI, and EPA therefore has reason to suspect that other submissions similarly may

inaccurately claim CBI. *See* 15 U.S.C. § 2613(f)(2)(B) (requiring that EPA "shall review" a confidentiality claim and require any claimant "to reassert and substantiate or resubstantiate the claim" if EPA "has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section").

B. In sharing information with the persons identified by TSCA § 14(d)(4)-(6), EPA should acknowledge and communicate when claims have not been reviewed and create a system to reflect changes in status.

As explained above, some of the information claimed confidential that EPA will share through these guidance documents may or may not merit protection under TSCA § 14. Specifically, EPA does not have to review *all* confidentiality claims, so some claims may never be reviewed. In addition, EPA's confidentiality program is a black box: There is no public evidence or indication that EPA has begun reviewing confidentiality claims under the Lautenberg Act, much less that it has met its obligations to review all chemical identity claims (with one exception) and 25% of all other claims. To the best of EDF's knowledge, EPA has not yet published a *single* determination on a CBI claim despite almost two years having passed since Congress mandated EPA reviews and that all such determinations be public. *See* 15 U.S.C. §§ 2613(g)(1)(describing EPA's rulings on confidentiality claims as "determinations"), 2625(j)(1) ("[EPA] shall make available to the public—all *** determinations *** under this title."). As a result, it seems very likely that much of the information EPA must share with persons under TSCA § 14(d)(4)-(6) will be "claimed" confidential but not yet reviewed by EPA.

EPA should create a system so that, when it shares information with persons under TSCA § 14(d)(4)-(6), EPA will disclose to those persons the status of the applicable CBI claims, as well as time period (where applicable) for which the information is designated to be protected from disclosure. Specifically, EPA should inform persons whether the information is:

- Claimed CBI but not reviewed by EPA; protected until date X (where applicable)[6]
- Claimed CBI and under review by EPA
- Claimed CBI and approved by EPA; protected until date X

This information will be helpful to both EPA and the recipient in understanding the status of the confidentiality claim. EPA should also promptly notify recipients of changes to that status which will affect the recipients' obligations and use of the information. For example, in some instances, EPA may determine that a claim is not warranted, and in those circumstances, the recipient of the information should promptly be informed that s/he no longer has to treat it as confidential.

[6] TSCA provides that most claims, unless withdrawn or otherwise found to be invalid, are subject to a 10-year time limit, unless renewed. Depending on the circumstances, the 10-year period starts upon either the date of assertion of a claim or the date of EPA's determination that a claim is warranted. 15 U.S.C. §§ 2607(b)(4)(D)(ii)(III), 2607(b)(5)(B)(iii)(III), 2613 (e)(1)(B)(i), 2613(e)(2)(B)(ii)(III)(aa), and 2613(f)(3).

C. EPA should also create a mechanism to allow recipients of the information to alert EPA to any errors or concerns about the legitimacy of the confidentiality claims *or* the accuracy or completeness of underlying information.

In addition, EPA should have an easy-to-use mechanism for recipients of claimed TSCA CBI to provide EPA additional information both about the confidentiality claims and about the chemical substances.

With respect to confidentiality claims, if a recipient of information discovers evidence that the information does not qualify for confidentiality, EPA should make it easy for those recipients to alert EPA to that new information. EPA has no sound basis for ignoring such relevant information, and ignoring relevant information is arbitrary and capricious. Notably, TSCA § 14(f)(2)(B) requires that EPA "shall review" a confidentiality claim and require any claimant "to reassert and substantiate or resubstantiate the claim" if EPA "has a reasonable basis to believe that the information does not qualify for protection from disclosure under this section." 15 U.S.C. § 2613(f)(2)(B). If EPA wants recipients to honor confidentiality claims and to have confidence in the system, it is important that EPA create an effective mechanism to ensure that recipients can call on EPA to correct oversights or errors.

In addition, while using the information received from EPA, the recipients of confidential information will often collect additional information about the chemical substances, and that information could significantly assist EPA in implementing TSCA. EPA should create an easy mechanism for recipients to report such additional information to EPA. Indeed, TSCA § 26(k) requires that in carrying out TSCA §§ 4, 5, and 6, EPA must consider "[r]easonably available information," and specifically that EPA "shall take into consideration information relating to a chemical substance or mixture, including hazard and exposure information, under the conditions of use, that is reasonably available to [EPA]." 15 U.S.C. § 2625(k). In a recent regulation relating to risk evaluations under TSCA, EPA interpreted "[r]easonably available information" in § 26(k) to mean "information that EPA possesses or can reasonably generate, obtain, and synthesize for use." 40 C.F.R. § 702.33 (promulgated at 82 Fed. Reg. 33,748 (July 20, 2017)). EPA should take the opportunity of these guidance documents to provide an easy mechanism for recipients of confidential information to report additional substantive information to EPA. Such information, if willingly submitted, would be reasonably available.

V. EPA needs to acknowledge the broader amendments to TSCA § 14 and accept that TSCA confidentiality is now narrower than confidentiality under Exemption 4 of FOIA.

In describing confidentiality under TSCA § 14, EPA's documents contain numerous misstatements of law, and EPA too often relies on its general FOIA regulations, which predate the 2016 Lautenberg Act's amendments that dramatically altered TSCA § 14. As a result, the guidance documents err in their description of both the substantive and procedural requirements for confidentiality under TSCA. As a general matter, EPA needs to accept that Congress consciously chose to impose more stringent substantive and procedural standards on confidentiality claims under TSCA, and that Congress called for wider disclosure of confidential information in this context. EPA needs to modify these guidance documents to provide an *accurate* description of confidentiality under TSCA § 14.

This problem is particularly apparent in the draft guidance document for state, local, and tribal governments. *See* SLT guidance p.9. EPA cannot impose an unfair burden on potential recipients of the information: recipients only need to protect confidential information to an extent "comparable" to the protections provided under TSCA § 14, not the broader protections of Exemption 4 of FOIA.

A. TSCA § 14 protects less information than FOIA Exemption 4.

i) *TSCA § 14 imposes additional substantive and procedural requirements on confidentiality claims beyond FOIA Exemption 4.*

TSCA § 14 now requires that TSCA confidentiality claims must meet numerous substantive and procedural requirements beyond those required by FOIA Exemption 4. The draft guidance documents often do not reflect these new requirements. Indeed, the draft government guidance document states that: "TSCA section 14 uses Exemption 4 of the Freedom of Information Act (FOIA) as the basic standard for eligibility for confidential treatment." SLT guidance p.9. This is wrong. And it has implications for the rest of the guidance; for example, EPA then states that: "a requesting government should have a law similar to Exemption 4 of the federal FOIA." SLT guidance p.9.

In fact, TSCA § 14 is substantially narrower than Exemption 4. 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]—(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) (emphasis added). As a result, to refuse to disclose information under TSCA § 14, EPA has to establish that information falls within FOIA Exemption 4, *and in addition*, EPA also has to determine that the information meets the requirements of TSCA § 14(c).

ii) *TSCA § 14(b) excludes entire categories of information from confidentiality.*

Furthermore, TSCA § 14(b) provides a number of express exclusions from TSCA § 14(a), so there are entire categories of information that are not confidential under TSCA § 14, regardless of whether they would otherwise qualify for confidentiality under Exemption 4 and § 14(c). 15 U.S.C. § 2613(b). Perhaps most importantly, information from health and safety studies (with two limited exceptions) are not confidential under TSCA § 14. 15 U.S.C. § 2613(b)(2).

EPA needs to clearly describe that information identified under TSCA § 14(b) is not eligible for protection. EPA should explain in the guidance how people can obtain the information available under TSCA § 14(b), particularly information from health and safety studies. If EPA clearly explains these issues, then it can use TSCA § 14(b) as an example of a mandatory disclosure requirement. But at present, EPA's description of those issues, in particular in paragraph 7 of the SLT guidance, is misleading. SLT guidance p.10.

iii) *EPA cannot rely on its general FOIA regulations or outdated CBI Manual.*

One consequence of these differences is that EPA cannot continue to rely on its general FOIA regulations to describe confidentiality requirements of TSCA § 14. When the draft guidance relies on these

provisions, it imposes too stringent a burden on state, local, and tribal governments. Similarly, EPA cannot rely on its *TSCA CBI Protection Manual* because it has not been updated to reflect the Lautenberg Act's substantial amendments to TSCA § 14.

Instead, EPA should include a clear and accurate description of confidentiality under TSCA § 14 (for example, in an appendix to the guidance documents) so that recipients of information are provided an accurate and complete depiction of what information is truly confidential under TSCA § 14.

In particular, EPA cannot require that state, local, and tribal governments provide the broad protections for confidentiality claims of FOIA Exemption 4 when TSCA § 14 itself does not allow EPA to withhold information on that basis. While a law similar to Exemption 4 certainly qualifies as "comparable" to TSCA § 14 for the purposes of TSCA § 14(d)—since it provides *broader* protections for information claimed to be confidential—state, local, and tribal governments may provide narrower protection and still qualify to receive confidential information under TSCA § 14(d)(4).

B. EPA cites to too loose a substantive standard for confidential information.

In the SLT guidance document, EPA cites to 40 C.F.R. 2.205 and 2.208 as providing an example of the substantive criteria that a government may impose on confidentiality claims. But this general FOIA regulation does not accurately describe confidentiality claims under TSCA § 14.

40 C.F.R. § 2.208 provides that information "is entitled to confidential treatment" if it meets certain criteria. 40 C.F.R. § 2.208. But § 2.208 does not include one of the criteria required for confidentiality by TSCA § 14. TSCA § 14(c)(1)(B)(iv) requires that a claim for confidentiality must be accompanied by, among other things, "a statement that the 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). In addition, TSCA also requires that, with certain exceptions, "a person asserting a claim to protect information from disclosure under this section shall substantiate the claim." *Id.* § 2613(c)(3). To implement these statutory requirements, EPA must require that persons asserting applicable confidentiality claims provide some substantiation that the claimed information is not readily discoverable through reverse engineering. Thus far, EPA has failed to implement these requirements through regulation.

Given that no accurate regulations are currently available, EPA should cite to TSCA § 14, 15 U.S.C. § 2613, to provide an example of the substantive and procedural criteria that state, local, and tribal governments may impose on confidentiality claims.

VI. EPA needs to limit confidentiality claimants to the rights specified in TSCA.

Congress created a detailed regime for processing requests under TSCA § 14(d)(4)-(6), and EPA also specified the limited rights of confidentiality claimants under those provisions. EPA should not deviate from those legal requirements and EPA should clearly articulate those requirements.

A. Congress specified the limited rights of confidentiality claimants in TSCA.

First, when EPA "intends to disclose information pursuant to subsection (d) *** [EPA] shall notify, in writing, the person that asserted the [confidentiality] claim *** of the intent of [EPA] to disclose the information *** . The notice shall be furnished by certified mail (return receipt requested), by personal delivery, or by other means that allows verification of the fact and date of receipt." 15 U.S.C. § 2613(g)(2)(A). Thus, Congress specified that EPA should promptly notify confidentiality claimants "of the intent of [EPA] to disclose the information." *Id.*

Second, for TSCA § 14(d)(4) and (d)(5), EPA "shall not disclose the information until the date that is 15 days after the date on which the person that asserted the claim *** receives notification." 15 U.S.C. § 2613(g)(2)(C)(i). Notably, Congress specifically chose to provide only 15-day notice before disclosure of this information, in contrast to the general 30 days provided in other circumstances, *id.* § 2613(g)(2)(B). Congress chose a short timeframe and EPA has a duty to disclose the information after the 15-day period. EPA should commit to disclosure immediately after that 15-day period has elapsed; Congress has not given EPA discretion to extend that time period.

For TSCA § 14(d)(6), Congress consciously chose *not* to require notice be given to confidentiality claimants prior to disclosure. Rather, "[EPA] shall notify the person that submitted the information that the information *has been* disclosed *as soon as practicable after disclosure of the information*." 15 U.S.C. § 2613(g)(2)(C)(ii) (emphases added). Thus, in the circumstances presented by TSCA § 14(d)(6), Congress intended for EPA to disclose the information as soon as possible and *before* providing notice to the confidentiality claimant.

Third, Congress consciously chose to foreclose administrative appeals of the determination to disclose information under these provisions. Instead, the sole opportunity for a confidentiality claimant to challenge disclosure is through a lawsuit in district court brought *before* the date on which the disclosure is mandated under TSCA § 14(g)(2)(C). 15 U.S.C. § 2613(g)(2)(D)(i) ("If a person receives a notification under this paragraph and believes the information is protected from disclosure under this section, before the date on which the information is to be disclosed pursuant to subparagraph (B) or (C) the person may bring an action to restrain disclosure of the information in" certain district courts.).

Fourth, EPA is not allowed to withhold requested information from state, tribal, and local governments under TSCA § 14(d)(4) pending the outcome of any judicial appeal. Congress specifically chose to restrict EPA from disclosing information pending judicial appeal as a general matter, but Congress also expressly stated that this nondisclosure requirement "shall not apply to disclosure of information described under subsections (d)(4) and (j)." 15 U.S.C. § 2613(g)(2)(D)(ii)(II). Congress thus intended for EPA to disclose information to governments pending the outcome of any appeal.

B. Confidentiality claimants have no right to review or comment on statements of need or agreements between EPA and persons under TSCA § 14(d)(4)-(6).

Congress specified that persons requesting information from EPA under TSCA § 14(d)(4)-(6) must enter "agreements" with EPA. 15 U.S.C. § 2613(d)(4), (d)(5), (d)(6)(B). Congress also specified that persons

requesting information from EPA under TSCA § 14(d)(5) must provide EPA with a written statement of need. 15 U.S.C. § 2613(d)(5). In the case of persons requesting information from EPA under TSCA § 14(d)(6), the confidentiality agreement and statement of need are to be provided to EPA only if requested by the confidentiality claimant, and "as soon as practicable, but not necessarily before the information is disclosed." 15 U.S.C. § 2613(d)(6)(B).

Confidentiality claimants have no right to review these agreements or statements or provide comment on them. *First*, the plain text, requiring an agreement between EPA and the requesting person, reflects that the requester and EPA must reach a mutually agreed-to arrangement. Agreement means "[a] coming together of parties in opinion or determination; the union of two or more minds in a thing done or to be done; a mutual assent to do a thing." Agreement, The Law Dictionary (2d ed.), https://thelawdictionary.org/agreement/. Such an agreement must result in a harmony between EPA and the requester, and it implies at most a negotiation between EPA and the requester. The content of such an "agreement" would not involve third-parties who might disrupt the negotiation. If Congress had intended for confidentiality claimants to be parties to these agreements or play a role in their negotiation, Congress would have provided some statutory direction governing their participation. Congress chose not to do so.

Second, TSCA § 14(g) provides limited notice and appeal rights for confidentiality claimants, and notably, *none* of those rights provide confidentiality claimants with any right to notice or comment on the statements or agreements described in TSCA § 14(d)(4)-(6). TSCA § 14(g) never refers to these statements or agreements. Thus, confidentiality claimants have no right to participate in the negotiation or review of these statements or agreements. When Congress creates a detailed regulatory scheme setting forth specific rights, the terms of the statute define those rights. *Cf. United States v. Bormes*, 568 U.S. 6, 14 (2012) ("Where a specific statutory scheme provides the accoutrements of a judicial action, the metes and bounds of the liability Congress intended to create can only be divined from the text of the statute itself.").

C. The SLT guidance deviates from TSCA's requirements.

EPA states that it will provide claimants with "the requesting government's written request to the affected business." SLT guidance p.9. This requirement deviates from TSCA in several key ways. *First*, Congress specified that EPA should notify confidentiality claimants only "of the intent of [EPA] to disclose the information," 15 U.S.C. § 2613(g)(2)(A). Congress did not give the confidentiality claimants any right to review *requests* from governments.

This distinction is crucially important. State, tribal, and local governments may seek confidential information to assist in their law administration and enforcement activities. EPA should not thoughtlessly reveal the nature of such requests to persons who may, for example, be undergoing investigation for public health violations or other legal violations. If Congress had meant for EPA to disclose this type of information to confidentiality claimants, Congress would have said so. It did not.

Second, Congress limited notification rights to "the person that asserted the [confidentiality] claim or submitted the request [for confidentiality]." 15 U.S.C. § 2613(g)(2)(A). As explained below in Part XII.A,

EPA's general FOIA regulations define "affected businesses" more broadly. But Congress was clear that *only* the person who claimed confidentiality had a right of notification (and thus appeal) under TSCA § 14.

Third, EPA suggests that it has a right to withhold information from the requesting government in the event of a legal challenge. *See* SLT guidance p.11 ("EPA *may* still disclose the information to the requesting government despite such a legal challenge unless EPA is enjoined from disclosing information.") (emphasis added). EPA does not have any such right to withhold the information from the requesting government. TSCA § 14(d)(4) requires that the information "shall be disclosed" to the requesting government. 15 U.S.C. § 2613(d)(4). Crucially, Congress chose to require EPA to withhold disclosure of information pending some judicial challenges *but* consciously chose to exempt disclosures under TSCA § 14(d)(4) from that requirement. *See* 15 U.S.C. § 2613(g)(2)(D)(ii)(II). Congress thus intended for EPA to disclose information to state, local, or tribal governments pending the outcome of any appeal, and EPA should disclose information in such circumstances; otherwise, EPA will be unlawfully rendering this exception to nondisclosure meaningless.

EPA needs to prominently note that claimants cannot block state, local, or tribal government access to the requested information even if they file an appeal under TSCA § 14(g)(2)(D). TSCA § 14(g)(2)(D)(ii)(II) reflects a conscious compromise, in which confidentiality claimants can get prior notice of, but cannot block, state, local, or tribal government access to their CBI.

VII. To avoid unreasonable delays in disclosing information, EPA needs to add deadlines to the process, and needs to expedite development of an electronic database and tracking system for information under TSCA § 14.

A. EPA needs to specify deadlines to ensure timely processing of requests for CBI access.

Currently, the guidance documents do not appear to include deadlines for EPA to take action on requests, notifications, and disclosures. To avoid unreasonable delays, EPA should set forth deadlines for each of these actions. Specifically, there are three potential periods at issue:

1) How long it will take EPA to process a request for information?
2) How soon EPA will notify confidentiality claimants of its intent to disclose? and
3) How soon EPA will disclose information after notifying the claimant?

TSCA provides general direction on the latter two deadlines, and those expectations of short deadlines should inform the first. The guidance documents should reflect these directions and specify tight deadlines so that EPA's staff understands the timeframes under which they need to work.

Processing requests: EPA should commit in its guidance to promptly process all requests for information it receives pursuant to TSCA § 14(d)(4)-(6). For TSCA § 14(d)(4) and (d)(5), EPA should commit to deciding on a request (and providing the required notification to claimants) within at most 5 business days of its receipt. Where a state, local, or tribal government has already been "pre-approved" for CBI access (pursuant to SLT guidance p. 11), EPA should commit to deciding on a request (and providing the

required notification to claimants) within at most 3 business days of its receipt. For TSCA § 14(d)(6), EPA should commit to processing the request within no more than 24 hours.

Providing notification: For TSCA § 14(d)(4) and (d)(5), EPA shall notify a confidentiality claimant of the intent to disclose information. *See* 15 U.S.C. § 2613(g)(2)(A). Congress' clear expectation was that EPA do so promptly once EPA forms the intent to disclose the information. Thus, as soon as EPA makes a decision to disclose, EPA should submit the notice to the claimant immediately, and, consistent with the deadline above for processing requests, in no case later than 5 business days after receiving the request (no later than 3 days after receiving the request from a state, local, or tribal government has already been "pre-approved" for CBI access).

Disclosing the requested information: For TSCA § 14(d)(4) and (d)(5), EPA must provide the claimant with 15 days notification. *Id.* § 2613(g)(2)(C)(i). Here again, Congress' clear expectation was that EPA disclose the requested information promptly once the 15-day period has expired. Indeed, Congress decided to make the timeframe shorter than for many other duties governing confidentiality: While the general rule for disclosures other than those under TSCA § 14(d)(4)-(6) is that EPA must disclose information 30 days after notifying a claimant, *id.* § 2613(g)(2)(B), Congress chose *tighter* deadlines for these provisions. Because disclosure is certain to occur for approved requests under § 14(d)(4) and likely to occur for approved requests under § 14 (d)(5) (barring the filing of a court challenge), EPA can and should be fully prepared to disclose the information once the notification period expires. EPA should set a firm deadline for disclosing the requested information not later than 1 business day after the 15-day notification period ends.

For TSCA § 14(d)(6), Congress actually requires EPA to disclose the information *before* notifying the confidentiality claimant, though EPA shall notify the claimant "as soon as practicable *after* disclosure of the information." 15 U.S.C. § 2613(g)(2)(C)(ii) (emphasis added). Given that this information is to be shared without even notifying the confidentiality claimant *and* it arises in the context of an "emergency," EPA should commit to disclosing information under this provision not more than 48 hours after receiving the request. Indeed, Congress did not even require requesters to submit the statement of need and confidentiality agreement *before* the information is disclosed. *See id.* § 2613(d)(6)(b)(ii) (requiring requester to "submit to [EPA] such statement of need and confidentiality agreement as soon as practicable, *but not necessarily before the information is disclosed*") (emphasis added). Thus, Congress wanted EPA to share the information quickly and typically without waiting to review the statement of need and agree to a confidentiality agreement. These provisions all indicate the Congress intended for EPA to act very quickly under TSCA § 14(d)(6). A 48-hour deadline for action is reasonable given these provisions.

B. EPA needs to expedite development of an electronic database and tracking system for information under TSCA § 14.

The 2016 amendments to TSCA imposed numerous new requirements on both EPA and CBI claimants with respect to assertion, substantiation, and review of CBI claims, as well as new obligations on EPA to share CBI with additional persons.

Providing timely and accurate responses to requests for access to CBI would be greatly facilitated by EPA expediting the development of a CBI management database and tracking system. It would also enhance EPA's ability to meet other obligations under TSCA § 14, including claim status, tracking of time periods for CBI protection, assignment and application of unique identifiers, and notification requirements.

As noted in Part I.C of these comments, EPA has an affirmative duty to, in consultation with the Centers for Disease Control and Prevention (CDC), "develop a request and notification system that, in a format and language that is readily accessible and understandable, allows for expedient and swift access to information disclosed pursuant to paragraphs (5) and (6) of subsection (d)." 15 U.S.C. § 2613(g)(3). Fulfilling this requirement can be achieved as part of the broader development of an electronic CBI management system, which can meet both internal and external needs under TSCA § 14.

VIII. EPA should clarify that references to state, local, and tribal governments always include agencies of such governments.

Each draft guidance document provides a definition of state and tribal government, but they do not clearly state that these entities include agencies of such governments. *See* SLT guidance p.5; NEM guidance p.4; EM guidance p.5. As a general rule, all three guidance documents should clarify that references to state, local, and tribal governments include agencies of such governments. Governments often work through their agencies, just as the federal government works through EPA. These three provisions sweep broadly to allow EPA to share information with governments, and Congress intended for these provisions to allow EPA to share information with the agencies through which those governments act. *See* 15 U.S.C. § 2613(d)(4)(information "shall be disclosed to a State, political subdivision of a State, or tribal government"); 15 U.S.C. § 2613(d)(5) (information "shall be disclosed to a health or environmental professional employed by a Federal or State agency or tribal government"); 15 U.S.C. § 2613(d)(6) (information shall be disclosed to a "public health or environmental official of a State, political subdivision of a State, or tribal government."); *see also* Cong. Rec. S7143 (daily ed. Oct. 6, 2015) (statement of Sen. Manchin) ("It ensures that doctors, first responders, and government health and environmental officials would have greater access to confidential business information to guarantee that those potentially exposed to harmful chemicals could receive the best possible treatment."). As a result, EPA may enter agreements with multiple state agencies from a single state, such as the Wyoming Department of Environmental Quality and the Wyoming Department of Health.

COMMENTS ON ISSUES APPLICABLE TO DRAFT SLT GUIDANCE

The following comments apply to EPA's draft state, local, and tribal government guidance.

IX. EPA should retain a pre-approval process and its definition of local government.

EDF supports EPA's decision to create a pre-approval process for state, local, and tribal governments. *See* SLT guidance p.6. This process will increase efficiency and flows from the statutory text's reference to such governments having "applicable agreements" with EPA. 15 U.S.C. § 2613(d)(4). In addition, EDF

supports EPA's decision to use the term "local government" as synonymous with "political subdivision of a state," and EPA's recognition that the statute sweeps broadly with this term. SLT guidance p.5. EPA correctly recognizes that the "term ordinarily includes a county, city, town, village, or school district, and, in many States, a sanitation, utility, reclamation, drainage, flood control, or similar district." SLT guidance p.5. It may also include many other entities, so EPA appropriately uses the expansive and non-exclusive word "includes."

X. State, local, and tribal governments do not need to show that the information is "necessary."

TSCA § 14(d)(4) requires EPA to disclose confidential information to state, tribal, and local governments "on written request, *for the purpose of administration or enforcement of a law*," if they meet certain requirements. 15 U.S.C. § 2613(d)(4) (emphasis added). Crucially, the information only needs to be "for the purpose of administration or enforcement of a law. *Id.* EPA's draft guidance document inaccurately suggests that the state, local, or tribal government must show that the information "is necessary for" those activities. SLT guidance p.6. But such governments need only show that the information is for the purpose of administration or enforcement; they need not show that the information *is necessary* for those efforts. The word "necessary" *never* appears in TSCA § 14(d)(4).

Importantly, Congress specifically included "necessary" requirements in *other* provisions of TSCA § 14(d), but it never mentioned it in TSCA § 14(d)(4). Indeed, TSCA § 14(d)(5) includes a requirement that requesting persons provide a "statement of need," but Congress chose not to include any such requirement for disclosure under TSCA § 14(d)(4). Thus, Congress signaled its intent for EPA to share information broadly with state, local, and tribal governments whenever that information will be used for the purposes of administration or enforcement of a law; such governments need not make any showing of need or necessity. The legislative history shows that Congress meant for EPA to share this information widely with other governments. *See, e.g.*, H.R. Rep. No. 114-176, at 29 (June 23, 2015) (authorizing disclosure to "State and local governments and tribal officials who request it for the purpose of administering or enforcing a law"); Cong. Rec. S8873 (daily ed. Dec. 18, 2015) (statement of Sen. Udall) ("Our bill *** gives States and health professionals access to confidential information to protect the public.").

In addition, even in the context of TSCA § 14(d)(5) and (d)(6), a "statement of need" only requires that the person have "a reasonable basis to suspect that the information is necessary for, *or will assist in*" certain activities. *Id.*§ 2613(d)(5)(B)(i) (emphasis added). Thus, even when a "statement of need" *is* required, requesters may obtain the information by showing that they have a reasonable basis to suspect the information would "assist" with the underlying activity. *None* of the requesters under TSCA § 14(d)(4)-(6) need to meet a showing of necessity or that the information is "necessary." EPA should modify the guidance documents to reflect the actual test laid out in the statute.

XI. State, local, and tribal governments need only have procedures for confidential information "comparable" to those provided by EPA under TSCA § 14.

State, local, and tribal governments need only "take appropriate measures, and ha[ve] adequate authority, to maintain the confidentiality of the information in accordance with procedures *comparable*

to the procedures used by [EPA] to safeguard the information" under TSCA § 14(d)(4) (emphasis added). As relevant here, "comparable" means "[a]ble to be likened to another; similar" or "[o]f equivalent quality; worthy of comparison." *Oxford American Dictionary* 352 (3d ed. 2010). Thus, governments need only have procedures able to be likened to those available under TSCA § 14, or similar to those measures. EPA has no authority to require that the measures be identical or even highly similar to those EPA provides under TSCA § 14. The purpose of TSCA § 14(d) is to ensure that EPA share confidential information with these governments while providing "comparable" protection of the confidential information. *See* 15 U.S.C. § 2613(d)(4). If EPA adopts too stringent a requirement for sharing the information, EPA will defeat Congress' purpose.

In addition, Congress legislated against a background of wide variation among the state, local, and tribal governments, and the choice of the word "comparable" showed that Congress wanted EPA to accept variable procedures for protection. Congress and the courts have "long recognized the role of the States as laboratories for devising solutions to difficult legal problems." *Ariz. State Legis. v. Ariz. Indep. Redistricting Comm'n*, 135 S. Ct. 2652, 2673 (2015) (quoting *Oregon v. Ice*, 555 U.S. 160, 171 (2009)); *New State Ice Co. v. Liebmann*, 285 U.S. 262, 311 (1932) (Brandeis, J., dissenting) ("It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country."). Different state, local, and tribal governments may devise different solutions to address the protection of confidential information. As long as those procedures are "comparable" to those required of EPA by TSCA § 14, EPA should accept them. EPA should not interfere with the functioning of these laboratories of democracy by unreasonably withholding crucial information.

EPA's draft guidance document varies in how well it captures this standard. In places, EPA correctly recognizes that state, local, and tribal governments need only have standards "similar to" federal law. *See* SLT guidance p.9. But in other places, EPA presents the federal standards as though they are binding or a bare minimum. *Id.*

For example, in paragraph 3, EPA describes "substantive criteria for determining confidentiality." *See* SLT guidance p.9. EPA states that the "criteria should include the following items." *Id.* While the items are reasonable examples, a government's procedures could be "comparable" without including each and every item. A better word than "should" would be "may" or "often." As explained above in Part III, because EPA is proceeding through nonbinding guidance, EPA should be careful to avoid using language of command.

As noted above, while a law similar to Exemption 4 certainly qualifies as "comparable" to TSCA § 14 for the purposes of TSCA § 14(d)—since it provides *broader* protections for information claimed to be confidential— state, local, and tribal governments that provide narrower protection should still qualify to receive confidential information under TSCA § 14(d)(4). But if a state, local, or tribal government provides protections equivalent to of those under Exemption 4, then they should *per se* qualify as "comparable." On this note, EPA cannot reasonably demand that governments provide any protections beyond those described in EPA's *TSCA CBI Protection Manual*.

In sum, EPA should clearly articulate that it will accept a reasonable amount of variation and will disclose information as long as the state, local, or tribal government has "comparable" procedures.

XII. The broader amendments to TSCA § 14 mean that government policies can be "comparable" to EPA's even if they mirror TSCA § 14 and not FOIA.

A. EPA should clarify that governments may require upfront substantiation instead of notice-and-comment and provide notice only to the businesses that submitted the information and claimed it confidential.

Relying on its general FOIA regulations, EPA states in its SLT guidance that governments should permit "affected businesses" to claim CBI and permit an opportunity for them to comment on such claims before disclosure. SLT guidance p.9. For purposes of TSCA § 14(d), such a notice-and-comment requirement is certainly "comparable" to the protections provided by TSCA § 14, but it is not the only acceptable option.

As written, EPA's draft guidance might give governments the impression that they cannot require upfront substantiation instead of a notice-and-comment opportunity. Under TSCA as amended, the Federal government requires upfront substantiation and need only provide *notice* to submitters of information who asserted a claim for confidentiality prior to any disclosure to state, local, or tribal governments. 15 U.S.C. § 2613(g)(2). The statute does not provide a full notice-and-comment process; the sole mechanism to appeal a denial of confidentiality is to file a lawsuit in district court. *Id.* § 2613(g)(2)(D). Moreover, state, local, and tribal governments need only provide procedures "comparable" to TSCA § 14. Thus, they could require upfront substantiation and provide notice, but they also may provide different procedures that accomplish the same basic goals. In addition, while state, local, and tribal governments may choose to provide notice-and-comment to all "affected businesses," the Lautenberg Act does not require such a broad notice opportunity.

One of the major amendments of the Lautenberg Act was a requirement that (with one set of exceptions) persons claiming confidentiality must concurrently substantiate the claim. *See* 15 U.S.C. § 2613(c)(3) ("[A] person asserting a claim to protect information from disclosure under this section shall substantiate the claim."). EPA is supposed to rule on many of those claims, and EPA is not required to provide any further notice-and-comment opportunities beyond the upfront substantiation requirement. *See id.* § 2613(g). Given that Lautenberg expressly requires upfront substantiation and allows rulings without any further opportunity for comment, any similar state, local, or tribal government procedures would be "comparable" under TSCA § 14(d)(4). EPA should clarify that upfront substantiation without further comment is an acceptable method for governments to provide comparable procedures.

In addition, EPA erroneously states that governments must provide notice-and-comment to "affected businesses" and "businesses" generally. Read expansively, EPA is suggesting that governments must provide notice-and-comment to *all* "businesses," though we expect that EPA does not actually mean that. EPA certainly is suggesting that governments must provide notice to "affected businesses," however, which EPA's general FOIA regulations define broadly to mean, "with reference to an item of business information, a business which has asserted (and not waived or withdrawn) a business

confidentiality claim covering the information, or a business which could be expected to make such a claim if it were aware that disclosure of the information to the public was proposed." 40 C.F.R. § 2.201(d).

Under the Lautenberg Act, Congress shifted the confidentiality requirements to protect only those persons who submit the information and concurrently make a claim for confidentiality. 15 U.S.C. § 2613(c)(1)(A). TSCA's provisions all reflect that CBI claims are company-specific and specific to the information the company submitted. TSCA now provides that: "[a] person seeking to protect from disclosure any information *that person submits* under this Act *** shall assert to [EPA] *a claim* for protection from disclosure concurrent with submission of the information." 15 U.S.C. § 2613(c)(1)(A) (emphases added). A person may only assert "a claim" for protection of the information "that person submits"; a person has no right to demand confidentiality for information submitted by another person. When asserting the claim, a person must also make numerous company-specific substantive assertions. *Id.* § 2613(c)(1)(B). A person must assert that they have "taken reasonable measures to protect the confidentiality of the information" and 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." *Id.* § 2613(c)(1)(B)(i), (iii). Thus, nothing in the text of TSCA is consistent with EPA's suggestion that claims are not company-specific. Indeed, these provisions indicate that the same type of information—such as specific chemical identity—could be CBI for one company and not for another, *e.g.*, if one company has taken sufficient steps to protect the information and another has not.

In addition, TSCA § 14(g) provides that EPA must provide notice of denial of a claim "to the person that asserted the claim" or made the request for nondisclosure, and only the person who made the confidentiality claim has appeal rights. 15 U.S.C. § 2613(g)(1)(B), (g)(2)(D). Given that the law only provides these protective rights to the submitters of information who concurrently make confidentiality claims, other governments need only provide an opportunity for notice-and-comment on confidentiality claims to such entities. EPA cannot require governments to sweep broadly to all "affected businesses".

B. The correct "judicial appeal" provisions for comparison are those under the Lautenberg Act.

EPA states that governments should provide an opportunity for judicial appeal of any denial of confidentiality. SLT guidance p.9. That requirement is consistent with TSCA, but EPA again cites to its general FOIA regulations that predate the 2016 amendments to TSCA. The better comparator would be the judicial review provisions of TSCA § 14 itself. *See, e.g.*, 15 U.S.C. §§ 2613(g)(2). Notably, for disclosures under TSCA § 14(d)(4), Congress only provided confidentiality claimants 15 days to appeal, *id.* § 2613(g)(2)(C)(i), not the 31 days described in the draft guidance based on 40 C.F.R. § 2.306(e)(3).

COMMENTS ON ISSUES APPLICABLE TO BOTH NEM GUIDANCE AND EM GUIDANCE

The following comments apply to both EPA's draft non-emergency guidance and its draft emergency guidance.

XIII. EPA needs to modify and add to the definitions in the NEM Guidance and EM Guidance to encompass all the persons that Congress intended to access information under TSCA § 14(d)(5)-(6).

A. EPA needs to expand its definition of "nurse" to include other members of the nursing profession.

EPA's proposed definition of "nurse" in both the NEM and EM guidance documents refers to nurse practitioners and registered nurses, but does not include, for instance, licensed professional nurses (LPNs), and does not specify whether it includes certified nurse-midwives or certified midwives. NEM guidance p. 4; EM guidance p. 4. Members of all these professions are certified and required to be licensed.[7] They are equally likely to need or be assisted by access to CBI, and should be added to the definition of "nurse" in each guidance document. This list is not exhaustive or all-encompassing because there are numerous types of professional nurses. EPA should adopt a broad definition with a non-exclusive "including" list of certain nurse practitioners.

TSCA § 14(d)(5) and (d)(6) refer to a "treating" and "treating or responding" "nurse." 15 U.S.C. § 2613(d)(5), (d)(6). "Treating" in this context refers to "[g]iv[ing] medical care or attention to; try[ing] to heal or cure." *Oxford American Dictionary* 1844 (3d ed. 2010). The focus is on the provision of medical care or attention to harm, and EPA should adopt an interpretation of "nurse" that reflects that focus, including the many types of nurses that may treat patients.

B. EPA needs to expand its definition of "physician" to include other professions that perform the same or similar medical care services.

Relatedly, TSCA § 14(d)(5) and (d)(6) refer to a "treating physician" and "treating or responding physician." 15 U.S.C. § 2613(d)(5), (d)(6). As with nurses, this language sweeps broadly to any physicians giving medical care or attention. Black's Law Dictionary defines "physician" as a "practitioner of medicine; a person duly authorized or licensed to treat diseases; one lawfully engaged in the practice of medicine, without reference to any particular school." Physician, The Law Dictionary (2d ed.), https://thelawdictionary.org/physician/. EPA should adopt a broad interpretation of physician that reflects that encompasses all physicians who give medical care or and attention. Thus, "physician" should include doctors of medicine, but also physician assistants, veterinarians, and dentists, as discussed below.

EPA's definition of "physician" in both the NEM and EM guidance documents excludes Physician Assistants, who furnish consultations and treat people and are often the first line of medical care,

[7] *See* Bureau of Labor Statistics, Licensed Practical and Licensed Vocational Nurses, https://www.bls.gov/oes/current/oes292061.htm (last visited Apr. 13, 2018); American College of Nurse-Midwives, Essential Facts about Midwives (Feb. 2016), http://www.midwife.org/Essential-Facts-about-Midwives.

especially in rural and underserved areas.[8] NEM guidance p. 4; EM guidance p. 4. Thus, they will often be the "treating or responding" physician. According to the American Academy of Physician Assistants, Physician Assistants are certified and licensed to practice medicine under the supervision of a physician.[9] Members of this profession are equally likely to need or be assisted by access to CBI, and should be added to the definition of "physician" in each guidance document.[10]

In addition, EPA should include veterinarians in its definitions of physician. The term is shorthand for veterinary *physician*, and such professionals practice veterinary *medicine*.[11] They receive comparable training and are subject to comparable licensing and certification requirements.[12] In addition, veterinarians may well be in a position of diagnosing or treating animals that have or may have been exposed to chemicals, whether companion animals, livestock, or wildlife.[13] Hence, they are equally likely to need or be assisted by access to CBI.

Just as doctors are licensed to treat diseases, dentists are also "licensed to diagnose and treat diagnose and treat problems with patients' teeth, gums, and related parts of the mouth."[14] Because dentists are licensed professionals with comparable training, and Federal law recognizes that both doctors of dental surgery and of dental medicine are physicians, EPA should include dentists in their definition of physician.

EPA should modify its definition of "physician" in each guidance document to read as follows:

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[8] *See* Nat'l Rural Health Ass., Policy Brief (April 2018), https://www.ruralhealthweb.org/NRHA/media/Emerge_NRHA/Advocacy/Policy%20documents/04-09-18-NRHA-Policy-Physician-Assistants-Modernize-Laws-to-Improve-Rural-Access.pdf (describing physician assistants as "indispensable providers in rural areas" and noting that 20% of U.S. population is rural but only 11% of physicians practice in rural settings).

[9] *See* Am. Acad. of Physician Assistants, What is a PA? (Feb. 2018), https://www.aapa.org/wp-content/uploads/2018/03/What-is-a-PA-Infographic-Legal-Size_3.22_FINAL.pdf; Bureau of Labor Statistics, Physician Assistants https://www.bls.gov/ooh/healthcare/physician-assistants.htm#tab-4 (last visited Apr. 16, 2018).

[10] Alternatively, EPA could include physician assistants within its definition of nurse or provide a third category of persons who meet the requirements specified in EPA's definition of physicians, *i.e.*, "a person legally authorized to practice medicine or surgery by the State in which s/he performs such function or action who furnishes consultation or treats a person for a specific medical problem." EM Guidance p.4. Either way, EPA should ensure that other health care professionals who often provide primary care to patients and effectively act as treating or responding physicians or nurses also can access CBI.

[11] *See* Bureau of Labor Statistics, *Occupational Outlook Handbook*, What Veterinarians Do, https://www.bls.gov/ooh/healthcare/veterinarians.htm#tab-2 (last visited Apr. 16, 2018).

[12] *See* Bureau of Labor Statistics, *Occupational Outlook Handbook*, Veterinarians https://www.bls.gov/ooh/healthcare/veterinarians.htm#tab-4 (last visited Apr. 16, 2018).

[13] *See, e.g.*, A. Bernard, et al., *The Belgian PCB/dioxin incident: analysis of the food chain contamination and health risk evaluation*, Environ. Res. (2002), https://www.ncbi.nlm.nih.gov/pubmed/11896663.

[14] Bureau of Labor Statistics, Dentists, https://www.bls.gov/ooh/healthcare/dentists.htm#tab-2 (last visited Apr. 16, 2018).

Physician: a physician (including a doctor of medicine, veterinary medicine, pathology or osteopathy, a doctor of dental surgery or of dental medicine, or a physician assistant, legally authorized to practice by the State in which s/he performs such function or action) who furnishes a consultation or treats a person or animal for a specific medical problem.

C. EPA needs to add a definition of "medical professional."

TSCA uses the term "medical professional," 15 U.S.C. § 2613(h)(1)(C), which EPA also uses but has not defined in its guidance documents. Though the phrase only appears in TSCA § 14(h), it cross-references TSCA § 14(d)(5) and (d)(6), and it is accompanied by an inclusive "including"-parenthetical mentioning emergency technicians and first responders. *Id.* Given these cross-references, it is best read to mean all the types of medical professionals who receive information under TSCA § 14(d)(5) and (d)(6). EPA should define the term in both guidance documents to include any medical professional receiving information under TSCA § 14(d)(5) and (d)(6), including any nurse or physician (as modified and expanded per our earlier comments), as well as "an emergency medical technician or other first responder" as specified in TSCA.

XIV. TSCA § 14(d)(5) and (d)(6) require EPA to reach *agreements* with requesters, and that language indicates that EPA cannot unilaterally impose specific terms on requesters.

Both guidance documents provide specific text of a confidentiality agreement and state or imply that a requester must sign that specific agreement.[15] NEM guidance p. 9; EM guidance p. 11. The non-emergency guidance states that "persons requesting access to TSCA CBI ... must also sign the following written confidentiality agreement." NEM guidance p. 8. The emergency guidance states: "The confidentiality agreement is as follows." EM guidance p. 11.

A. EPA should include a model agreement that it will always accept.

In each guidance document, EPA should provide a model agreement that it will always accept. Having a default agreement that requires no negotiation will increase efficiency and allow both requesters and EPA to reach agreement without negotiation when appropriate.

B. The agreements are just with EPA.

TSCA's text makes it clear that the requester enters the agreements with EPA. *See* 15 U.S.C. § 2613(d)(5)(requiring that requester "agrees to sign a written confidentiality agreement with [EPA] ***"; 15 U.S.C. § 2613(d)(6)(requiring that requester "agree to sign a confidentiality agreement, as described in paragraph (5) ***"). That text clearly identifies two parties to the agreements; the confidentiality claimant(s) are *not* parties to the agreements. As explained above in Part VI, Congress provided confidentiality claimants with specific and limited rights under TSCA § 14, and Congress did not provide them with any right to review or comment on these agreements. *See supra* in Part VI.B.

[15] In the emergency guidance EPA acknowledges that signing a confidentiality agreement with EPA is only required "if requested by a person who has a claim with respect to the information" being disclosed. 15 U.S.C. § 2613(d)(6)(B).

C. EPA cannot require requesters to sign a fixed, pre-determined confidentiality agreement.

Nonetheless, EPA cannot and should not compel requesters to sign only its current proposed agreement or any other fully pre-specified confidentiality agreement. First, TSCA requires only that the requester "*agrees to sign a* written confidentiality agreement with [EPA]." 15 U.S.C. § 2613(d)(5), (d)(6)(B) (emphasis added). This language indicates that the requester has an active role in "agreeing" to the terms, and in context, the indefinite article suggests that EPA must be open to different types of confidentiality agreements. After all, a requester may "agree" to signing one type of written confidentiality agreement and not another. In addition, the term "agreement" connotes that two parties reach concurrence on an issue, not that one dictates terms to the other. *See supra* at Part VI.B.

Second, there may be legitimate reasons why a particular requester wishes or needs to alter the specific terms or language of a confidentiality agreement. EPA's guidance should be modified to provide such latitude. EPA should characterize its text as a model agreement that is always acceptable to EPA. But EPA should clarify that requesters can suggest modifications to its terms as appropriate.

Third, with respect to people obtaining information under TSCA § 14(d)(5), Congress expressly recognized that recipients might need to use information for purposes beyond those articulated in the original statement of need, so Congress provided that they could also use such information "as otherwise may be authorized by the terms of the agreement." *Id.* § 2613(d)(5)(C). To execute that language, EPA will have to be open to negotiation of additional terms in response to medical professionals' requests. EPA cannot impose a straightjacket agreement on recipients where it does not allow them to negotiate such additional terms.

Fourth, with respect to people obtaining information under TSCA § 14(d)(6), Congress expressly authorized EPA to disclose information *before* the requester has entered an agreement. *See* 15 U.S.C. § 2613(d)(6)(B)(ii) (directing a requesting person to "submit to [EPA] such statement of need and confidentiality agreement as soon as practicable, *but not necessarily before the information is disclosed*") (emphasis added). In the emergency context, requesters will sometimes need information in a very quick timeframe. Such requesters should have the right to negotiate modifications to the model agreement if appropriate; they should not be locked-into a model agreement after the fact.

D. EPA should not impose onerous obligations in confidentiality agreements that exceed the requirements of the statute.

EPA's draft confidentiality agreement text includes a provision that requesters who are medical professionals and disclose TSCA CBI to a patient or person authorized to make medical decisions on behalf of the patient "will advise that person that the information has been claimed confidential by a business and should not be further disclosed except as authorized by that business or by TSCA section 14." NEM guidance p. 9; EM guidance p. 11.

No such provision appears in TSCA. While some stakeholders in the debate over TSCA reform wanted such a provision, others opposed it as overly complicated, oppressive, intrusive, and constraining on the health provider-patient relationship: How, for example, can a doctor be expected to explain the terms

of a statement of need or confidentiality agreement s/he has with EPA to a patient? In the end, Congress did not include any such requirement in the final legislation. The law expressly provides for medical professionals to disclose CBI to their patients in the course of diagnosis or treatment. To minimize interference with the ability of these medical professionals to deliver health care, the law exempts this action from criminal penalties otherwise applicable to willful disclosures of CBI. *See* 15 U.S.C. § 2613(h)(1)(C). The law does not impose any requirement that the medical professional inform the patient about the confidentiality of the information, nor does it direct the medical professional to provide instructions to the patient on maintaining confidentiality.

In contrast, EPA's proposed language provides that medical professionals should tell patients that they must identify and negotiate terms with confidentiality claimants before repeating information they've learned as part of their treatment. But Congress specified precisely the types of rights that confidentiality claimants have, and Congress did not provide them with any authority to manage the speech of patients receiving care. In contrast, Congress expressly did contemplate that the medical professionals under TSCA § 14(d)(5) *may* negotiate with the confidentiality claimant to use information beyond the scope of the terms defined by the agreement with EPA. *See* 15 U.S.C. § 2613(d)(5)(C) (allowing use of information beyond purposes asserted in statement of need "as otherwise may be authorized *by the terms of the agreement* [with EPA] *or* by the person who has a claim under this section with respect to the information") (emphases added). But two aspects of that scheme are particularly noteworthy. First, medical professionals may negotiate such terms with EPA directly without engaging the confidentiality claimant at all; Congress used the disjunctive "or" to indicate that either approach was acceptable. Second, only the medical professional has to negotiate such terms with either EPA or the confidentiality claimant. Congress put no limitations on the patients receiving the information.

EPA should not deviate from Congress's carefully crafted scheme. In particular, the patients receiving this information have important, protected interests in the right to speak about their medical situation *and* in the right to seek out additional medical care while retaining medical privacy (*i.e.*, the right to discuss their medical situation with other providers without having to discuss their medical situation with private businesses). Congress weighed these unique and special interests and struck a particular balance. EPA should not assume that businesses' interests in confidentiality outweigh these interests when Congress found otherwise. In addition, this provision would largely be unworkable unless EPA were to develop a system to coordinate the conversations between patients and confidentiality claimants. We note EPA has not even taken the steps necessary to develop the electronic systems required by TSCA.

EPA has not provided any rationale for its inclusion of an additional provision that is not in the law, nor has EPA addressed its practicability. EPA should remove this provision from its guidance documents.

EPA's draft confidentiality agreements also include the following certification clause: "I certify that the statements I have made in this agreement and all attachments thereto are true, accurate, and complete." NEM guidance p. 9; EM guidance p. 12. This language is not required under TSCA, and is unreasonably onerous. It lacks even a qualifying clause such as "to the best of my knowledge." Furthermore, a requester's ability to know that all of the information s/he has provided is "true,

accurate, and complete" may be limited, especially as it relates to statements of need, where the law only requires that the requester have "a reasonable basis to suspect" certain circumstances exist. 15 U.S.C. §§ 2613(d)(5)(B), (d)(6)(A). The requester may have limited or no ability discern whether all information on which s/he is relying is true, and especially whether it is complete.

When Congress added these provisions to TSCA, Congress noted that these provisions are "modeled on a similar program established in the Emergency Planning and Community Right to Know Act (EPCRA)." S. Rep. 114-67, at 23 (June 18, 2015). While these provisions differ from those in EPCRA in some key ways, EPCRA provides a good model for addressing certification. In that context, EPA only requires that "[t]he request includes a certification signed by the health professional stating that the information contained in the statement of need is true." 40 C.F.R. § 350.40(d)(1)(v).

EDF urges that EPA strike its current language from both guidance documents. If EPA chooses to retain it, EPA should at least modify it to read as follows: "I certify that, to the best of my knowledge, the statements I have made in this agreement and all attachments thereto are true."

XV. EPA needs to provide an electronic option for requests for access to CBI.

Remarkably, EPA has indicated it will not provide any electronic option for health and environmental professionals to request access to TSCA CBI. EPA states that such requests can be made only by mail or delivery service in non-emergency situations (NEM guidance p. 7), and by email, fax, phone call, or messenger for emergency situations (EM guidance p. 9).

The law requires EPA to develop a "request and notification system" for health and environmental professionals to use that is "readily accessible" and provides "expedient and swift access" to CBI requested in both non-emergency and emergency situations. 15 U.S.C. § 2613(g)(3). Yet EPA states only that it is "considering" developing such an electronic request and access system, and provides no timeline or deadline for doing so (p. 7 of the NEM guidance). The law also requires that EPA consult with the Centers for Disease Control (CDC), yet EPA provides no acknowledgment of that requirement or any indication that it has even initiated such consultation.

It boggles the mind that in 2018 EPA proposes not to provide an electronic option for handling such requests.

EPA must expedite actions to comply with these provisions of the law, and in the meantime needs to provide an electronic option for requests to be made. At the very least, pending development of an electronic system, non-emergency requests should not, as is suggested in the NEM guidance, be limited to mail or delivery service, and should also be accepted via email, fax, phone, or messenger as EPA indicates it will provide in its EM guidance.

XVI. Where EPA provides information to a requester, it should always be followed up with a written response.

The NEM guidance states: "In some circumstances, it might be most efficient for EPA to simply provide the information orally, over the phone, and in other circumstances, the information may be provided in writing, and/or via electronic access." NEM guidance p. 7.

Similarly, the EM guidance states: "In some circumstances, it might be most efficient for EPA to simply provide the information orally, over the phone, and in other circumstances, the information may be provided in writing, and/or via electronic access." EM guidance p. 9. Earlier on the same page the EM guidance states: "Telephonic or other requests made orally will be memorialized in writing by EPA."

EPA should modify these sentences to consistently make clear that whenever EPA provides information orally, EPA will also then share the information in writing with the requester.

XVII. EPA should not impose CBI handling obligations not required under TSCA or other laws.

EPA's draft guidance documents imply that requesters are to take measures to preserve the confidentiality of the CBI they receive that go well beyond statutory requirements and are unreasonable. EPA has not provided any basis for including provisions such as that requesters should consider "destroying such written or electronic copies once the need for the information subsides (by, for example, shredding, burning, or degaussing)." NEM guidance p. 10; EM guidance p. 10.

At the very least EPA needs to clearly characterize such measures as merely recommendations that are not required under any applicable law. Instead, it has included them directly alongside statutory requirements.

COMMENTS ON ISSUES SPECIFIC TO NEM GUIDANCE

XVIII. EPA has inconsistently cited statutory requirements applicable to requesters of CBI in non-emergency situations.

In its NEM guidance, EPA has not consistently reflected the language of the statute itself in describing obligations of non-emergency requesters in establishing the basis for their requests for access to TSCA CBI. For example, EPA states: "This document also provides guidance on how to determine whether the information is necessary for or will assist with nonemergency medical diagnosis or treatment, or response to an environmental release under section 14(d)(5)." NEM guidance p. 2. EPA omits from this statement a key qualifying clause that is in the statute: that the requester need only have "*a reasonable basis to suspect*" that the information is necessary for or will assist with nonemergency medical diagnosis or treatment. 15 U.S.C. § 2613(d)(5)(B) (emphasis added).

EPA's guidance needs to accurately track the statute and avoid, whether intentionally or unintentionally, creating a higher standard for gaining CBI access than Congress set.

COMMENTS ON ISSUES SPECIFIC TO EM GUIDANCE

XIX. EPA has proposed definitions for several key terms that are too narrow and do not reflect the statute.

A. EPA's definition of "agent of a poison control center" is narrower than that in the statute.

In its EM guidance, EPA unlawfully defines an "agent of a poison control center" to only include persons employed "by a State, local, or tribal poison control center." EM guidance p. 4. TSCA does not limit "poison control centers" to those run by a state government, local government, or tribe. 15 U.S.C. § 2613(d)(6). The definition proposed by EPA would likely exclude a number of poison control centers (PCC), such as, the PCC at the Children's Hospital of Alabama, the PCC at the Children's Hospital of Philadelphia, the Puerto Rico Poison Control Center, and the ASPCA Animal Poison Control Center.[16] *See* http://www.aapcc.org/centers/?name=&states_served.

B. EPA's definition of "first responder" is narrower than that in the statute.

EPA unlawfully defines a "first responder" to only include persons "duly authorized by a Federal agency, State, political subdivision of a state, or tribal government." EM guidance p. 4. TSCA does not limit "first responders" to those duly authorized by a state government, local government, or tribe; it includes but is not limited to such individuals. 15 U.S.C. § 2613(d)(6); *see also* A. SCALIA & B. GARNER, READING LAW: THE INTERPRETATION OF LEGAL TEXTS 132 (2012) ("The verb *to include* introduces examples, not an exhaustive list."). Many first responders are employed or contracted by private entities and EPA should not rewrite this provision of TSCA so as to exclude them from accessing CBI. On a related matter, EPA includes the following statement in two places in the emergency guidance: "A treating or responding physician, nurse, agent of a poison control center, public health or environmental official of a State, political subdivision of a state, or tribal government." (EM guidance pp. 2, 6). This statement does not accurately track the statute, where the phrase "of a State, political subdivision of a state, or tribal government" only modifies "public health or environmental official." 15 U.S.C. § 2613(d)(6). EPA's statement unlawfully broadens its applicability to require that a "treating or responding physician, nurse, or agent of a poison control center" must also be government-affiliated. EPA needs to correct these statements.[17] EPA correctly states the provision under section II.A., where it essentially quotes the statutory language. EM guidance p. 6.

C. EPA's definition of "health professional" is overly narrow and not consistent with the statute.

EPA's draft guidance includes a definition of "health professional" (EM guidance p. 4), a term that does not appear in TSCA § 14(d)(6). This term does appear in one other place in EPA's draft guidance,

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[16] *See* LOCAL POISON CENTERS, http://www.aapcc.org/centers/ (last visited Apr. 16, 2018) (identifying the nation's poison centers); *see also* ANIMAL POISON CONTROL, https://www.aspca.org/pet-care/animal-poison-control (last visited Apr. 16, 2018).

[17] This correction could be made simply through the following insertions: "A treating or responding physician, nurse, or agent of a poison control center, or a public health or environmental official of a State, political subdivision of a state, or tribal government."

however: in the definition of "medical emergency," where it is used appropriately in a broad and general manner: "any unforeseen condition which a *health professional* would judge to require urgent and unscheduled medical attention." EM guidance p. 4 (emphasis added). In contrast, EPA's definition of the term is inappropriately narrow, as it limits such a person to "a Federal, State, or tribal government employee assigned to an agency or other government subdivision." This provision of the law extends to numerous health professionals – physicians, nurses, agents of poison control centers, and first responders – who need not be government employees, all of whom have the training to make the requisite judgment. And in its plain meaning, "health professional" does not suggest any limitation to those who work for government.

EPA should broaden the definition of "health professional" by removing its limitation to government employees and including physicians, nurses, agents of poison control centers, and first responders.

D. EPA's definition of "medical emergency" needs to be extended to include potential impacts.

EPA's definition of "medical emergency" (EM guidance p. 4) needs to be much more qualified to encompass conditions that *could* result in *potentially* serious symptom(s) or that constitute a *potential*, not just actual, threat to health. The current definition implies a level of certainty that simply will not exist in the great majority of emergency situations. The statutory language of TSCA § 14(d)(6) reflects this lack of certainty by requiring requesters only to have "a reasonable basis to suspect" certain conditions exist. 15 U.S.C. § 2613(d)(6).

EPA should modify its definition of "medical emergency" along the following lines:

> *Medical Emergency*: any unforeseen condition which a health professional would have a reasonable basis to suspect could ~~would judge to~~ require urgent and unscheduled medical attention. Such a condition is one which could result~~s~~ in sudden and/or potentially serious symptom(s) constituting a potential threat to a person's physical or psychological well-being and which a health professional would have a reasonable basis to suspect could require~~s~~ immediate medical attention to prevent possible deterioration, disability, or death.

E. EPA's definition of "public health emergency" is overly focused on biological agents and inappropriately would limit the term to large-scale catastrophic events.

EPA's definition of "public health emergency" (EM guidance p. 4) places an odd emphasis on biological agents: "infectious disease outbreak," "bioterrorist attack." EPA's examples should in addition relate to chemical agents, such as a significant release of a chemical agent (e.g., due to a train derailment) or a terrorist attack involving release of a chemical. Furthermore, EPA's use of the terms "disaster" and "catastrophic event" connote a massive scale of an event in order to qualify as a public health emergency, whereas local or even smaller scale events (e.g., involving a single school or neighborhood) should be included. EPA needs to provide a better definition that is relevant to TSCA information and does not set such a high bar. Black's Law Dictionary defines an "emergency" as simply a "[s]ituation requiring immediate attention and remedial action. Involves injury, loss of life, damage to the property,

or catastrophic interference with the normal activities. A sudden, unexpected, or impending situation." Emergency, The Law Dictionary (2d ed.), https://thelawdictionary.org/emergency/

XX. EPA's requirements for the statement of need appear to exceed what the statute requires.

Several provisions in section II.B.1, 2 and 3 of the emergency guidance seem to state or imply that a requester would need to provide what amounts to a statement of need before being able to gain access to CBI. These provisions all start: "At the time that the request is made, EPA will ask the requester to affirm that in the requester's official capacity as [insert position], the requester has a reasonable basis to suspect that ***." EM guidance pp. 7-8. This language invokes a phrase "has a reasonable basis to suspect" that is intended to be addressed in the statement of need, but in each instance EPA states that the requester must affirm this basis "at the time that the request is made," whereas the law only requires that a statement of need be submitted "as soon as practicable, but not necessarily before the information is disclosed." 15 U.S.C. § 2613(d)(6)(B)(ii). In addition, the statement of need is only required "if requested by a person who has a claim with respect to the information." 15 U.S.C. § 2613(d)(6)(B).

In each of these three sections, EPA goes on to state: "As described in Section IV of this document, an emergency requester may also be required to provide a written statement of need, and to sign a written confidentiality agreement, if the business that made the CBI claim asks for such statement." EM guidance pp. 7-8. Each of these provisions again need to note that, even where requested, the statement of need is to be submitted "as soon as practicable, but not necessarily before the information is disclosed."

Immediately after the first occurrence of the language just discussed, EPA states: "Note: Each request for TSCA CBI in an emergency situation should include an explanation or background to explain how the information requested relates to the emergency." EM guidance p. 7. Later in the same paragraph EPA adds: "To the extent that a request does not include sufficient background to explain how the information requested relates to the emergency, EPA may deny the request, or ask the requester to provide additional information." No such requirements or denial authority are specified in the statute, and to the extent they relate to the statement of need, EPA has no basis to require such information as part of the request or deny a requesting lacking it. EPA should not impose requirements on requesters that are not authorized under the statute. To obtain the information, a requester need only have "a reasonable basis to suspect" that "a medical, public health, or environmental emergency exists" and *either* that "the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment" *or* "1 or more individuals being diagnosed or treated have likely been exposed to the chemical substance or mixture concerned, or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred." 15 U.S.C. § 2613(d)(6)(A). It is completely unclear why EPA would need information going beyond those factors.

In section IV.A, EPA states: "In addition, the emergency requestor should attach or refer to the eligibility, justification, and description of the emergency information that s/he previously provided to

EPA (as set out in Section III.B-D of this document)." EM guidance p. 11. It is not clear what EPA is referring to by use of the term "justification." If EPA means "statement of need," it should use that term. Otherwise it needs to explain what is meant by the term and what basis there is in the statute to require it.

In section IV.B, EPA's text of a confidentiality agreement refers in two places to the "statement of need." EM guidance p. 11. EPA needs to acknowledge in each case that a statement of need is required only if requested by a claimant.

XXI.EPA's provisions relating to allowed disclosure of CBI by requesters contain several inconsistences.

EPA states in section II.B.1: "At the time that the request is made, EPA will ask the requester to ... confirm their understanding that the CBI released may be used only for the emergency purpose for which it is requested, and that the information will not be disclosed to any person not entitled to receive it." EM guidance p. 7. This provision fails to include two important caveats. First, the law provides that the requested CBI may be used for other purposes "as otherwise may be authorized by the terms of the [confidentiality] agreement or by the person who has a claim under this section with respect to the information." 15 U.S.C. § 2613(d)(5)(C). EPA needs to include these exceptions here. Second, EPA fails to note here (though it is noted later) the applicability of TSCA § 14(h)(1)(C), which provides an exception to this prohibition and associated criminal penalties for a medical professional (including an emergency medical technician or other first responder) to disclose CBI to a patient treated by the medical professional, or to a person authorized to make medical or health care decisions on behalf of such a patient, as needed for the diagnosis or treatment of the patient. This important exception needs to be included here.

In three other places in the guidance where EPA does acknowledge this provision of the statute, EPA states it incorrectly. EPA states that "medical professionals may disclose the information to their patient or to persons authorized to make medical decisions on behalf of the patient, as set out in section 14(h)(1)(C)." (EM guidance pp. 7, 10 and 11). In each case, "medical decisions" needs to be changed to "medical <u>or health care</u> decisions" as provided for in the statute. 15 U.S.C. § 2613(h)(1)(C).

XXII. EPA has omitted important statutory language in provisions describing emergency situations.

In section II.B.2 of the guidance, EPA omits important language that is in the statute. First, the heading for part 2. reads: "*The information is necessary for emergency or first-aid diagnosis or treatment*." EM guidance p. 7. However, the corresponding provision of the statute reads: "The information is necessary for<u>, or will assist in,</u> emergency or first-aid diagnosis or treatment." 15 U.S.C. § 2613(d)(6)(A)(ii)). EPA needs to track the statute here.

Second, EPA states later in this section "For guidance, emergency requesters should be able to describe how the circumstances of their request meet the following criteria:

- There is an identifiable patient or patients in need of diagnosis or treatment;

- The patient(s) was or may have been exposed to a chemical substance(s) or mixture(s)...."

EM guidance p. 7. The second bullet omits a key additional condition that is in the statute (TSCA § 14(d)(6)(A)(iii)), and should instead read:

> "The patient(s) was or may have been exposed to a chemical substance(s) or mixture(s) or a serious environmental release of or exposure to the chemical substance or mixture concerned has occurred."

As written, EPA is deviating from the clear statutory language and imposing too heavy a burden on requesters of information. EPA should follow the language of the statute instead.

XXIII. EPA has omitted important statutory language in a provision describing claimant notification.

In section IV, EPA states: "Section 14(g)(2)(C) requires EPA, as soon "as practicable," to notify the person who made the CBI claim of the disclosure." EM guidance p. 10. In fact the statute states such disclosure is required "as soon as practicable *after disclosure of the information*." 15 U.S.C. § 2613(g)(2)(C)(ii) (emphasis added). Thus, Congress has specified that the disclosure of the information should occur before notification of the confidentiality claimant. Again, EPA needs to track the statute.

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