

March 12, 2018; public review draft.

**Access to Toxic Substances Control Act Confidential Business Information:
*A **DRAFT** guide for access to TSCA CBI for medical and environmental
professionals in non-emergency situations***

Issued by the United States Environmental Protection Agency, Office of Chemical Safety and Pollution Prevention.

DISCLAIMER

This Guidance does not constitute rulemaking by the United States Environmental Protection Agency (EPA), and cannot be relied on to create a substantive or procedural right enforceable by any party in litigation with the United States. Non-mandatory language such as “should” provides recommendations and does not impose any legally binding requirements.

The Toxic Substances Control Act (TSCA) statutory provisions and EPA regulations described in this document contain legally binding requirements for access to TSCA CBI. This document is not a regulation itself, nor does it change or substitute those provisions and regulations. While EPA has made every effort to ensure the accuracy of the discussion in this guidance, the obligations of EPA and the regulated community are determined by statutes, regulations, or other legally binding requirements which supersede this guidance document.

Interested persons are free to raise questions and objections about the substance of this guidance and the appropriateness of the application of this guidance to a particular situation. EPA may make changes in this document at any time without public notice.

Preface:

The Toxic Substances Control Act of 1976 (TSCA) was amended in June of 2016. The amendments, known as the Frank R. Lautenberg Chemical Safety for the 21st Century Act, changed and expanded many parts of TSCA. Among these changes, under TSCA section 14(d) (15 U.S.C. 2613(d)), is an expansion of the categories of people who may now access TSCA Confidential Business Information (CBI). TSCA CBI is information submitted to EPA under TSCA for which a business has made a claim of business confidentiality. This information is protected from disclosure until the business withdraws the CBI claim, until the CBI claim expires, until EPA determines that the claim is not entitled to confidential treatment, or as authorized under TSCA and EPA regulations. Under section 14(d)(5) (15 U.S.C. 2613(d)(5)), TSCA authorizes disclosure to environmental, health, and medical professionals, if the requester provides a written statement of need and agrees to sign a written confidentiality agreement. TSCA section 14(c)(4)(B) (15 U.S.C. 2613(c)(4)(B)) requires that EPA develop guidance concerning the “content and form of the statements of need and agreements required” under section 14(d)(4), (5), and (6); Section 14(d)(5) requires that the statement of need and confidentiality agreement be consistent with this guidance. Disclosure is further conditioned that the person requesting the information will not use it for any purpose other than the needs asserted in the statement of need, except as otherwise authorized by the confidentiality agreement, or by the person who made the CBI claim.

This document provides guidance for access to TSCA CBI under section 14(d)(5) in a nonemergency situation by the following categories of requesters:

- Health professional employed by a Federal or State agency or Tribal government;
- Environmental professional employed by a Federal or State agency or Tribal government;
or
- Treating physician or nurse.

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), and addresses the following issues:

- (1) Determining whether you are eligible for access to TSCA CBI under section 14(d)(5);
- (2) How to request access to CBI; and
- (3) What information to provide in the required written statement of need and the confidentiality agreement.

Guidance for states, tribes, subdivisions of states, as well as for medical and environmental professionals and other first responders in an emergency situation, are addressed in separate documents:

Access to Toxic Substances Control Act Confidential Business Information:

A guide for access to TSCA CBI in emergency situations [\[insert link\]](#)

Access to Toxic Substances Control Act Confidential Business Information:

A guide for access to TSCA CBI for state, local, and tribal governments [\[insert link\]](#)

Table of Contents

- I. Definitions**

- II. Eligibility for Accessing TSCA CBI in a Nonemergency Situation**
 - A. *Who may request TSCA CBI in a nonemergency event*
 - B. *Disclosure in a “nonemergency situation”*
 - C. *Justification: identifying the reasonable basis*

- III. How to Request and Access CBI**
 - A. *Where to request CBI*
 - B. *Verification of eligibility*
 - C. *Describing the information sought and circumstances of the request*
 - 1. *Written statement of need*
 - 2. *Confidentiality agreement*
 - D. *Notice and waiting period*
 - E. *Handling CBI information received from EPA*

I. Definitions

Environment: includes water, air, and land and the interrelationship which exists among and between water, air, and land and all living things.

Environmental Professional: a Federal, State, or tribal government employee assigned to an agency or other government subdivision principally concerned with protection of the environment, natural resources, wildlife, and/or human health (for example, a state department of environmental quality or environmental protection, or a state department of health).

Health Professional: a Federal, State, or tribal government employee assigned to an agency or other government subdivision principally concerned with human health matters, such as a state health department, a state department of health services, or the federal Department of Health and Human Services.

Nurse: a nurse (nurse practitioner or registered nurse who performs such services as such individual is legally authorized to perform in the State in which such services are performed) who furnishes a consultation or treats a person for a specific medical problem.

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

Release: any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment (including the abandonment or discarding of barrels, containers, and other closed receptacles containing any hazardous substance or pollutant or contaminant).

State: any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, the Canal Zone, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Tribal government: any Indian Tribe, band, nation, or community recognized by the United States Secretary of the Interior and exercising substantial governmental duties and powers.

TSCA: the Toxic Substances Control Act, 15 U.S.C. 2601, et seq.

TSCA Confidential Business Information (TSCA CBI): 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.

II. Eligibility for Accessing TSCA CBI in a Nonemergency Situation

Summary

According to TSCA section 14(d)(5), you must meet the following requirements to access TSCA CBI in a nonemergency situation:

Who: You must be one of the following:

- A health professional employed by a Federal or State agency or tribal government,
- An environmental professional employed by a Federal or State agency or tribal government,
- or
- A treating physician or nurse.

Justification: You assert in a statement of need that you have a reasonable basis to suspect that:

- The information is necessary for, or will assist in, either:
 - The diagnosis or treatment of 1 or more individuals; or
 - Responding to an environmental release or exposure; and
- One 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.

Purpose: You must agree to use the information exclusively for the health or environmental needs asserted in the statement of need, and to sign a written confidentiality agreement.

Note that EPA cannot disclose the information until after 15-day notice to the entity that made the CBI claim.

A. Who may request TSCA CBI in a nonemergency event

Under TSCA section 14(d)(5), the following persons may request CBI in a nonemergency situation:

- (1) Health professional employed by a Federal or State agency or tribal government;
- (2) Environmental professional employed by a Federal or State agency or tribal government; or
- (3) Treating physician or nurse.

Contractors of State or tribal governments are not considered to be persons “employed by” a State agency or tribal government, and therefore may not be given access as a health or environmental professional. However, a treating physician or nurse is not required to be employed by a Federal or State agency or tribal government, so a treating physician or nurse who is a contractor may be given access under this section. In addition, contractors might be eligible to access CBI pursuant to section 14(d)(4) or section 14(d)(6). For more information, please consult the guidance documents pertaining to those sections, listed in the Preface to this document.

B. *Disclosure under section 14(d)(5) limited to “nonemergency situations”*

Among other conditions, section 14(d)(5) applies in “nonemergency situations” (i.e., any situation that does not qualify as a medical, public health, or environmental emergency within the meaning of section 14(d)(6)(i) or otherwise require the requested information for the purposes set forth in section 14(d)(6)(ii)-(iii)). For access to CBI in “emergency situations,” eligible requesters should consult the procedures set forth in section 14(d)(6), and which are further explained in another guidance document, “Access to Toxic Substances Control Act Confidential Business Information: *A guide for access to TSCA CBI in emergency situations.*” [\[insert link\]](#)

In addition, health or environmental professionals employed by a State, political subdivision of a state, or by a tribal government may use the access provisions described in TSCA section 14(d)(4) when requesting access to the CBI for the purposes of administering or enforcing a law. For more information on section 14(d)(4), please refer to another guidance document, “Access to Toxic Substances Control Act Confidential Business Information: *A guide for access to TSCA CBI for state, local, and tribal governments.*” [\[insert link\]](#)

Federal employees seeking to gain access to TSCA CBI should note that TSCA section 14(d)(1) provides for CBI access for federal employees more generally, and may wish to look into whether their agency already has made arrangements with EPA for access to TSCA CBI.

C. *Justification: identifying the reasonable basis*

In order to justify a request for access to TSCA CBI in a nonemergency situation, requesters must attest in a written statement of need that they have a reasonable basis to suspect that:

1. The information is necessary for, or will assist in, the diagnosis or treatment of one or more individuals who have been exposed to the chemical substance or mixture concerned

Or

2. The information is necessary for, or will assist in, responding to an environmental release or exposure which has occurred with respect to the chemical substance or mixture concerned.

At the time that the request is made, EPA will ask the requester to confirm his/her understanding that the information disclosed to him/her can only be used for the purpose asserted in the written statement of need, except as may be authorized by the terms of the confidentiality agreement, or by the person who made the CBI claim.

III. How to Request and Access CBI

A. *Where to request CBI*

To request access to CBI information, contact by mail or delivery service:

Director, Information Management Division
Office of Pollution Prevention and Toxics
Office of Chemical Safety and Pollution Prevention
William Jefferson Clinton Building
1200 Pennsylvania Avenue, N. W.
Mail Code: 7407M
Washington, DC 20460

Requests for access will be evaluated by the EPA Office of Chemical Safety and Pollution Prevention, in consultation with the EPA Office of General Counsel.

EPA is also considering developing an electronic request and access system for TSCA CBI information, using EPA's Central Data Exchange (CDX) platform. Prospective TSCA CBI requesters will first register for CDX (<https://cdx.epa.gov/>). Registering for CDX will provide a means for EPA to verify the requester's identity, and provide an efficient, electronic means of making the request for information. Instructions for registering with CDX and making electronic requests for CBI access will be made available when such system is developed.

If the request for disclosure is granted, EPA will provide instructions for accessing the data. 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.

B. *Verification of eligibility*

When the CBI is requested, EPA must verify that the requester falls within one of the above-mentioned categories of requesters eligible for access to CBI under section 14(d)(5). To do this, requesters should provide the following information:

- (1) The requester's first and last name
- (2) The requester's position
- (3) The requester's employer and/or affiliation
- (4) A representation that the requester is certified to perform the services relevant to the requester's position
- (5) The requester's contact information (email address, phone number and/or mailing address)

EPA reserves the right to request further information at the time of the request for the TSCA CBI, or after the TSCA CBI has been released. Any false statements or misrepresentations made to EPA at the time of the request may result in liability under 18 U.S.C. 1001.

C. Describing the information sought and circumstances of the request

Requesters should provide a description of the information requested and the circumstances of the request. For example, one might request the specific chemical identity information for a chemical publically identified only by trade name, or health and safety data for a particular substance or class of substances. The requester should also explain the facts or circumstances surrounding his request (e.g., describe the environmental release or exposure event). Such details may help EPA to identify information relevant to a particular request, and help to support the assertions in the statement of need. On reviewing a request for information, EPA may also contact the requester to request further information, or to clarify the request.

In addition, TSCA requires that the requester provide a written statement of need, as well as agree to a written confidentiality agreement. Note that according to section 14(d)(5)(A), these statements of need and confidentiality agreements must be consistent with this document.

1. Written statement of need

According to section 14(d)(5), the written statement of need shall be a statement that the person has a reasonable basis to suspect that:

(1) the information is necessary for, or will assist in—

(a) the diagnosis or treatment of one or more individuals; or

(b) responding to an environmental release or exposure; **and**

(2) One 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.

In their request for information, the requester must include the relevant part of this statement of need.

For a human exposure, the statement of need should be as follows:

I have a reasonable basis to suspect that the requested information is necessary for, or will assist in, the diagnosis or treatment of one or more individuals, and one or more individuals being diagnosed or treated have been exposed to the chemical substance or mixture concerned.

For an environmental release, the statement of need should be as follows:

I have a reasonable basis to suspect that the requested information is necessary for, or will assist in, responding to an environmental release or exposure, and an environmental release of or exposure to the chemical substance or mixture concerned has occurred.

2. Confidentiality agreement

Prior to disclosure of the information, and as required by section 14(d)(5), persons requesting access to TSCA CBI under these circumstances must also sign the following written confidentiality agreement:

The undersigned hereby agrees to the following terms and conditions associated with this request for access to and use of confidential business information pursuant to section 14(d)(5) of TSCA:

I will have access to certain Confidential Business Information (CBI) submitted under the Toxic Substances Control Act (TSCA), 15 U.S.C. 2601, et seq. This access has been granted in accordance with TSCA section 14(d)(5), for the purposes established in that section, and in the statement of need pertaining to this disclosure of TSCA CBI to me.

The TSCA CBI may be used only for the purposes stated in my statement of need, except as otherwise authorized by the terms of this agreement or by the person who has a CBI claim under TSCA section 14 with respect to this information. Use of this information for any other purpose than that included in the statement of need will not be undertaken until a separate written statement of need for access to the information has been submitted and access pursuant to that need is granted.

I understand that under TSCA section 14(h), 15 U.S.C. 2613(h), I am liable for a possible fine and/or imprisonment for up to one year if I willfully disclose TSCA CBI to any person not authorized to receive it. I further understand that disclosure of CBI is limited by TSCA section 14, and by this agreement, except 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). When disclosing TSCA CBI to a patient or person authorized to make medical decisions on behalf of the patient, I 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.

I understand that I have an obligation to protect any TSCA CBI information provided to me from further disclosure by taking appropriate precautions against loss, theft, or unauthorized disclosure. For example, physical documents and portable electronic media should be stored in a locked cabinet when not in use, and TSCA CBI should not be duplicated more than is necessary for the purpose of meeting the health or environmental need specified in the request.

I certify that the statements I have made in this agreement and all attachments thereto are true, accurate, and complete. I acknowledge that any knowingly false or misleading statement may be punishable by fine or imprisonment or both under 18 U.S.C. 1001.

D. Notice and waiting period

Once the above requirements have been met, and EPA has determined that release of the information can be made to the requester, TSCA section 14(g)(2) requires that EPA provide 15 days' notice to the submitter before disclosing the information.

E. Handling CBI information received from EPA

The requester should be especially aware that the CBI information is only to be disclosed to those who are authorized to receive it. In fact, persons that willfully disclose such CBI to unauthorized persons are

liable for a possible fine and/or imprisonment for up to one year, under section 14(h) of TSCA. In cases where the CBI information has been provided in written or electronic form, the requester should ensure that the information is secured and stored in such a manner as to prevent disclosure to unauthorized persons, and should consider (consistent with applicable legal requirements) destroying such written or electronic copies once the need for the information subsides (by, for example, shredding, burning, or degaussing).