

March 12, 2018; public review draft.

**Access to Toxic Substances Control Act Confidential Business Information:  
A *DRAFT* guide for access to TSCA CBI in 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, or until EPA determines that the CBI claim is not entitled to confidential treatment, or as authorized under TSCA and EPA regulations. Under section 14(d)(6) (15 U.S.C. 2613(d)(6)) TSCA authorizes disclosure of TSCA CBI in the event of an emergency to certain persons. 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).

This document provides guidance for access to TSCA CBI under section 14(d)(6) in the event of an emergency to the following categories of requesters, if specific conditions are met:

- 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 (including 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).

This document also discusses:

- (1) What constitutes an emergency;
- (2) Whether you are eligible for access to TSCA CBI under section 14(d)(6);
- (3) How to request access to CBI during an emergency;
- (4) What information is pertinent to a statement of need and confidentiality agreement, and how to submit these documents, if requested.

Guidance for health and environmental professionals seeking access to TSCA CBI in non-emergency situations, and for state and tribal government access for purposes of administering a law, are covered in separate documents:

Access to Toxic Substances Control Act Confidential Business Information:

*A guide for access to TSCA CBI for medical and environmental professionals in non-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 an Emergency**

- A. *Who may request TSCA CBI in an emergency*
- B. *Emergency event*
  - 1. *A medical, public health, or environmental emergency exists*
  - 2. *The Information is necessary for emergency or first-aid diagnosis or treatment*
  - 3. *Likely exposure or serious environmental release*

### **III. During the Emergency: Requesting CBI**

- A. *Where to request CBI in an emergency*
- B. *Verification of eligibility*
- C. *Describing the information sought*
- D. *Describing the emergency and circumstances; required affirmations*
- E. *Handling the information during and after the emergency*

### **IV. Additional Requirements at the Request of the Person Who Made the CBI Claim**

- A. *Written statement of need*
- B. *Confidentiality agreement*

## **I. Definitions**

Agent of a poison control center: person employed by a State, local or tribal poison control center.

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

Environmental Emergency: includes the environmental impacts of industrial and/or technological incidents, and of natural disasters and complex emergencies, that require technical support in order to respond effectively to minimize negative environmental impacts, and to recover quickly and sustainably.

First responder: 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. In this context, the term “duly authorized” means the individual is employed by or works for the entity, which could include as a volunteer.

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.

Medical Emergency: any unforeseen condition which a health professional would judge to require urgent and unscheduled medical attention. Such a condition is one which results in sudden and/or serious symptom(s) constituting a threat to a person's physical or psychological well-being and which requires immediate medical attention to prevent possible deterioration, disability, or death.

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.

Public Health Emergency: an emergency need for health care (medical) services to respond to a disaster, significant outbreak of an infectious disease, bioterrorist attack or other significant or catastrophic event. A public health emergency may include but is not limited to, a public health emergency declared by the Secretary of Health and Human Services under 42 U.S.C. 247d, or a declaration of a major disaster or emergency under the Robert T. Stafford Disaster Relief and Emergency Assistance Act (Stafford Act), 42 U.S.C. 5121-5206.

Public health or environmental official: an employee of a State, political subdivision of a State, or tribal government employee assigned whose job duties are principally concerned with protection of the environment, natural resources, wildlife, and/or human health. For example, an employee of a state health department or department of environmental protection.

Serious environmental release: any spilling, leaking, pumping, pouring, emitting, emptying, discharging, injecting, escaping, leaching, dumping, or disposing into the environment requiring emergency response.

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 an Emergency

### Summary

According to TSCA section 14(d)(6), you must meet the following requirements to access TSCA CBI in the event of an emergency:

**Who:** You must be one of the following:

- 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

- A first responder who is trained in urgent medical care or other emergency procedures, including a police officer, firefighter, or emergency medical technician.

**Emergency:** the disclosure must be in the event of an emergency.

**Justification:** you must have a reasonable basis to suspect that:

- a medical, public health, or environmental emergency exists;
- the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; or
- one 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.

### *A. Who may request TSCA CBI in an emergency*

Section 14(d)(6) authorizes disclosure of TSCA CBI 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 (including 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).

Federal employees seeking to gain access to TSCA CBI for official duties 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 in accordance with EPA regulations at 40 C.F.R. 2.306(h).

### *B. Emergency event*

In addition to the fact that the request must take place in the context of an emergency event, the emergency requester must have a reasonable basis to suspect that at least one of three conditions exist:

*1. A medical, public health, or environmental emergency exists*

TSCA Section 14(d)(6) authorizes disclosure of TSCA CBI in cases of a “medical, public health, or environmental emergency.” For guidance, emergency requesters should review the definitions for medical, public health, and environmental emergency included in the Definitions in Section I, and be able to describe how the circumstances of their request meet these definitions of emergencies.

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 a medical, public health, or environmental emergency exists; and
- 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.

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.

**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.** Requesters should note that the person(s) that made the CBI claim will be given notice of the disclosure, and that on request by that person, the requester may be required to provide the reason for the request in a written statement of need to be submitted to EPA, and also may be required to sign a written confidentiality agreement. Finally, requesters should note that section 14(h) of TSCA prohibits further disclosure of TSCA CBI to any other person not entitled to receive it (e.g., persons that have not been granted access pursuant to the provisions of section 14(d)), with a limited exception for medical professionals (who may, pursuant to TSCA section 14(h)(1)(C), disclose the information to their patient or to persons authorized to make medical decisions on behalf of the patient). 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.

*2. The information is necessary for emergency or first-aid diagnosis or treatment*

TSCA section 14(d)(6) also authorizes disclosure of TSCA CBI if the emergency requester has a reasonable basis to suspect that the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment.

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);
- The emergency requester is providing emergency or first aid diagnosis or treatment to the patient(s).
- The information is necessary for, or will assist with, such emergency diagnosis or treatment.

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 the information is necessary for, or will assist in, emergency or first-aid diagnosis or treatment; and
- confirm his/her understanding that 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.

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.

### *3. Likely exposure or serious environmental release*

TSCA section 14(d)(6) also authorizes disclosure of TSCA CBI if the emergency requester has a reasonable basis to suspect that one 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.

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 and the patient was likely exposed to the specific chemical substance(s) or mixture(s) that is the subject of the request; OR
- A serious environmental release of or exposure to the specific chemical substance(s) or mixture(s) that is the subject of the request has occurred.

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 one 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; and
- confirm his/her understanding that 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.

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 who made the CBI claim asks for such statement.



### III. During the Emergency: Requesting CBI

#### A. *Where to request CBI in an emergency*

Emergency requests for CBI access should be directed to EPA Headquarters, via email, fax, phone call, or messenger, using the contact information listed below. Telephonic or other requests made orally will be memorialized in writing by EPA. Capacity for making electronic requests is being developed and will be made available in the future.

Requests may be directed to:

#### **TSCA Hotline**

Phone: 202-554-1404

Fax: 202-554-5603

E-mail: [tsc hotline@epa.gov](mailto:tsc hotline@epa.gov)

#### **EPA Headquarters**

Director, Information Management Division  
Office of Pollution Prevention and Toxics  
Office of Chemical Safety and Pollution Prevention  
William Jefferson Clinton Building East, Rm. 6120C  
1200 Pennsylvania Avenue, N. W.  
Mail Code: 7407M  
Washington, DC 20460  
Phone: 202-564-0970  
Fax: 202-564-7470

#### **EPA emergency TSCA CBI access contacts**

The current list of staff contacts is available on EPA's website, at [\[insert link\]](#).

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 requestor falls within one of the above-mentioned categories of emergency requesters eligible for access to CBI under section 14(d)(6). 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*

Requesters will also need to provide a brief description of the information requested. For example, one might request a list of all substances reported to be produced at a particular facility, or health and safety data for a particular substance or class of substances. EPA may ask the requester for additional information or further clarification, if necessary.

*D. Describing the emergency and circumstances; required affirmations*

As described in Section II, the CBI disclosure must be in the event of an emergency for which access to TSCA CBI is necessary. The emergency requester should describe the emergency situation, and how the information requested relates to that situation. Further, as noted in Section II.B, the emergency requester must have a reasonable basis to suspect that at least one of three circumstances apply, so must affirm such suspicion and circumstance, as well as his/her understanding of the limited use and further disclosure permitted for such CBI.

*E. Handling the information during and after the emergency*

The emergency requester should be especially aware that the CBI 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, 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). In cases where the CBI 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).

**IV. Additional Requirements at the Request of the Person Who Made the CBI Claim**

When EPA provides an emergency requester with CBI, EPA is required to take further action, which may also extend to the person who made the request for CBI. Section 14(g)(2)(C) requires EPA, as soon “as practicable,” to notify the person who made the CBI claim of the disclosure. If that person so requests, section 14(d)(6)(B)(i) requires that the emergency requester provide to EPA a written statement of need and sign a confidentiality agreement, “as soon as practicable, but not necessarily before the information is disclosed.” According to section 14(d)(6), the written statement of need and confidentiality agreement shall be as described under section 14(d)(5) (nonemergency situations), including the requirement under section 14(d)(5)(A) that all statements of need and confidentiality agreements must be consistent with this document.

In the event of such a request from the person that made the CBI claim, EPA will notify the emergency requester and provide instructions for providing the statement of need and confidentiality agreement to EPA. Further guidance on the statement of need and confidentiality agreement follows.

*A. Written statement of need*

The statement of need should be one or more of the following, as applicable:

At the time the information was/is requested, an emergency event was/is underway, and I had/have a reasonable basis to suspect that a medical, public health, or environmental emergency existed/exists.

At the time the information was/is requested, an emergency event was/is underway, and I had/have a reasonable basis to suspect that the requested information was/is necessary for, or would/will assist in the emergency or first-aid diagnosis or treatment.

At the time the information was/is requested, an emergency event was/is underway, and I had/have a reasonable basis to suspect that one or more individuals being diagnosed or treated had/has 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 had/has occurred.

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).

*B. Confidentiality agreement*

The confidentiality agreement is as follows:

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)(6) of TSCA:

I have or will have access to certain Confidential Business Information 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)(6), 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.

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 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 emergency purpose for which it was requested.

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.