

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY Notice for Toxic Substances Control Act (TSCA) Inspections

NOTICE REGARDING PROPRIETARY/CONFIDENTIAL BUSINESS INFORMATION (CBI) SUBMITTED TO OR COLLECTED BY EPA IN CONNECTION WITH INSPECTIONS AND OTHER COMPLIANCE MONITORING

For information submitted to or obtained by the U.S. Environmental Protection Agency (EPA or Agency) during or after an inspection (or other compliance monitoring), regulated entities (e.g., businesses, facilities, etc.) may assert a confidentiality claim on information that it believes is a trade secret or as privileged or confidential commercial or financial information, which is protected under Exemption 4 of the Freedom of Information Act (FOIA) at 5 U.S.C. § 552(b)(4). This type of information is commonly referred to as CBI or proprietary business information (PBI). For consistency purposes, the term CBI will be used within this document. Under section 14 of TSCA, regulated entities (e.g., businesses, facilities, etc.) have a right to claim certain information submitted to the EPA in connection with an inspection (or other compliance monitoring) as CBI. 15 U.S.C. § 2613. This document provides instructions for asserting a CBI claim, under TSCA, on the business information that you provided to EPA during or after its inspection based on the time limitations defined below.

EPA is giving you this Notice so that you have the opportunity to request confidential treatment of your business information in order to ensure that EPA properly handles your business' CBI claims. If your business believes that any information that EPA will be viewing or collecting during the inspection of your business may be CBI, EPA requests that a representative of your business who has the authority to claim that information as CBI, read, fill out and sign this Notice. You must read and follow all instructions for properly giving EPA notice of your CBI claim. If you have questions about this Notice, you or a representative of your business with the authority to assert the CBI claim may request clarification from the EPA inspector or call the contact name that the inspector will give you with this Notice. EPA has also created a Questions and Answers document for this Notice that you may find helpful and is available at: https://www.epa.gov/compliance/cbi-notice-information-collected-during-epa-inspections-or-other-compliance-monitoring

If a CBI claim does not accompany the information submitted to EPA, or is not submitted within 10 calendar days following an inspection, as described in Paragraph (A)(1)(b), below, then the Agency may make the information available to the public without further notice. For example, the Agency may make inspection reports available to the public, including through this website at https://echo.epa.gov. Also, EPA may be required by law to release the information to the public.¹ For example, the FOIA requires the disclosure of Agency records that have been requested by a FOIA request unless that information falls within a FOIA exemption. However, EPA does not release information claimed as CBI to the public in response to a FOIA request. In addition, EPA is required under section 14 of TSCA to routinely review (and approve or deny) all but some exceptional CBI claims for chemical identity, and a representative subset, comprising at least 25 percent, of other types of TSCA CBI claims. 15 U.S.C. § 2613(g). Information that you claim as CBI in accordance with TSCA section 14 will be held as such until the CBI claim is withdrawn, expires, or is denied by EPA, in accordance with TSCA section 14 and 40 C.F.R. Part 2, Subpart B.

¹ Information covered by a CBI claim will be disclosed by EPA only to the extent of, and by means of, the procedures set forth in 40 C.F.R. Part 2, Subpart B

(A) Procedures to claim confidential treatment for information provided to EPA.

(1) You may assert a CBI claim covering part or all of the information submitted to or obtained by EPA: (a) at the time of the inspection; (b) within 10-calendar days² following the inspection for information submitted to or obtained by EPA during the inspection; or (c) at the time of submittal, if you submit information requested before or after the inspection.

(2) If you fail to assert a CBI claim before an inspection, during an inspection, or within the 10-calendar day period following the inspection, the information may be made available to the public by EPA without further notice to the business.

(3) EPA's CBI regulations are at 40 C.F.R. Part 2, Subpart B (sections 2.201-2.311). See https://www.ecfr.gov.

(B) Method and time of asserting business confidentiality claim.

(1) Under TSCA section 14(c), you are required to substantiate each CBI claim (with some exceptions, described in TSCA section 14(c)(2)), provide certain certification statements, and, for CBI claims concerning chemical identity, provide a structurally descriptive generic name. All of this information must be provided at the time the information claimed as CBI is submitted to EPA. More information on how to assert a claim under TSCA may be found at <u>https://www.epa.gov/tsca-cbi</u>.

(2) A business that is submitting information to EPA may assert a business confidentiality claim by highlighting, bracketing, boxing, or circling the information claimed as CBI, and marking the page or document with language such as *trade secret, proprietary, company confidential, PBI, or CBI.* You may also provide a "sanitized" or non-confidential version of the document, with all CBI removed to facilitate identification and handling of CBI by EPA.³ If your business requests confidential treatment only until a certain date or until a certain event happens, then please indicate this at the time your business makes its CBI claim.

The Notice includes a box (page 4) that you or the inspector may use to list and generally describe the CBI claims; add an attachment if more space is needed.

(3) For documents that EPA inspectors collect or copy during the inspection, a representative of the facility should provide a general description of information that is claimed as CBI in those documents when provided to the inspector. Substantiation, certification, and generic name(s) (when applicable) may be provided to EPA following the inspection, but must be received by EPA within 10 calendar days after the inspection. Similarly, assertions that photos taken by EPA include or may include CBI should be made at the time of the inspection by a representative of the facility. Such assertions should generally describe what is considered CBI by the business, for example, specific equipment or processes. Substantiation of these CBI claims must be provided within 10 calendar days following the inspection. CBI claims to documents and photos taken or collected during the inspection that are not substantiated within this 10-calendar day timeframe or are otherwise not complete according to TSCA section 14(c), will be considered by EPA to have been withdrawn. Substantiation should be directed to the address for the EPA inspector identified on the sheet attached to this notice.

² The 10-calendar day period begins on the day after an inspection concludes. For example, if the inspection of your business commenced on Monday and concluded on Tuesday, the 10-calendar day period begins on Wednesday. If the 10-calendar day period ends on a weekend day or a holiday your claim must be postmarked, or EPA contacted by telephone by the next business day. In certain instances EPA may find it necessary to disclose the information obtained during the inspection and not claimed as CBI before the 10-calendar day period expires, and as such, EPA may provide the affected business less than 10-calendar days following an inspection to assert a CBI claim.

³ You should indicate, but not black out, white out or remove, all CBI in the documents you submit to EPA so that the CBI remains visible for EPA to read. Only marking the document or page as confidential or the like is not sufficient to assert a proper CBI claim. In addition to submitting the document with legible CBI, you may also submit a copy of the document with the CBI blacked out or removed, but you may not submit only a document with the CBI blacked out or removed (a "sanitized copy."). EPA treats the sanitized copy as a publicly available document.

(C) Substantiation of business confidentiality claim.

Unless the information is exempt from the substantiation requirement under TSCA section 14(c)(2), substantiation must be provided with TSCA CBI claims at the time they are asserted and submitted to the agency (but note the 10-calendar day period discussed in paragraph (B) for materials collected during an inspection). EPA has developed several submission type-specific and general templates that may be used to provide substantiation (use of the templates is recommended, but not required) and has provided additional guidance on what to include in a substantiation on the EPA TSCA CBI webpage: <u>https://www.epa.gov/tsca-cbi</u> The questions included in 40 C.F.R. § 2.204(e)(4) and the substantive criteria at 40 C.F.R. § 2.208 may also serve as a useful guide to what to include in a TSCA CBI substantiation.

(D) Certain information not entitled to confidential treatment.

Information that is publicly available at the time of inspection, or that is required to be disclosed to the public by law, is not entitled to confidential treatment and should not be claimed as CBI. While this is not a comprehensive list, the following types of information generally are not protected as CBI: information that is publicly available; information that was submitted to a federal, tribal, state or local government that was not claimed as CBI; information prohibited by law as CBI, such as effluent data, emissions data, or health and safety data in health and safety studies (see, e.g., TSCA section 14(b)). If a business makes a claim on any such information, EPA may make a determination under 40 C.F.R. § 2.204(d)(2) that the information is clearly not entitled to confidential treatment. See Attachment A, Questions and Answers about this Notice, for some examples of what is and is not entitled to confidential treatment.



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY PROPRIETARY/CONFIDENTIAL BUSINESS INFORMATION NOTICE FOR TSCA INSPECTIONS

Facility:	
Facility Address:	
Facility Representative with authority to make a CBI claim (print name & title):	Inspection Number:
	Date:
	Signature:
	Phone/email:
EPA Inspector (print):	Date:
Address: [mailing or courier address appropriate for inspector and/or inspector's Document Control Officer]	Phone:
	Email:

I have received this Notice and **DO NOT** make any CBI claim on the documents and information I have provided to EPA at this time.

I understand that, within 10-calendar days of the date of this inspection, if I determine that any of the documents and information I provided to EPA are CBI, I may send a written notice to the EPA inspector (address and email listed above) identifying the specific information I wish to claim as CBI.

I further understand that if no CBI claim was made at the time of the inspection or within the 10-calendar day period following this inspection, the information may be made available to the public by EPA without further notice to the business. See 40 C.F.R. 2.203.

I have received this Notice and **DO** make a CBI claim regarding the documents and information listed below that I have provided to EPA.

I hereby certify to the best of my knowledge and belief that all information entered on this form is complete and accurate.

I further certify that, pursuant to 15 U.S.C. § 2613(c), for all claims for confidentiality made with this submission, all information submitted to substantiate such claims is true and correct, and that it is true and correct that

- *i.* My business has taken reasonable measures to protect the confidentiality of the information;
- *ii.* I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
- iii. I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my business; and

iv. I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.

Any knowing and willful materially false, fictitious, or fraudulent statement or representation is subject to criminal penalty pursuant to 18 U.S.C. § 1001.

Part B of this Notice explained how to identify information claimed as CBI. You or the inspector may use this box to
list and generally describe any CBI claims. For clarity, please be as specific as possible.

Example: Internal layout of facility.

(Revised: XX/XX/XXXX)

Attach additional sheets, if needed.

Original to EPA / Copy to Facility