

Addressing TSCA Section 14 Substantiation Requirements

Webinar, July 13, 2017, 1:00 pm



PURPOSE OF TODAY'S WEBINAR

- To assist industry understanding of Agency expectations concerning compliance with the TSCA section 14 CBI substantiation requirements
- Mechanics of providing CBI substantiations

2016 TSCA AMENDMENTS

The Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act

- The 2016 amendments to the CBI provisions of TSCA:
 - Impose the requirement that EPA must review and make determinations regarding the validity of CBI claims
 - Impose new requirements on TSCA submitters, who make CBI claims
 - Certification
 - Substantiation
 - CBI claim is for specific chemical identity: a structurally descriptive generic name

Access the source: [https://www.epa.gov/tsca-cbi/cbi-claims-and-reviews-under-tsca#get overview](https://www.epa.gov/tsca-cbi/cbi-claims-and-reviews-under-tsca#get%20overview)

JANUARY FEDERAL REGISTER NOTICE

- On January 19, 2017, EPA announced an interpretation of TSCA section 14(c)(3) as requiring substantiation of non-exempt CBI claims at the time the information claimed as CBI is submitted to EPA. See 82 FR 6522 (1/19/2017)
- Approaches based on submission date:
 - Submissions received on or after March 21st
 - Submissions received before March 21st

Access the Source: <https://www.gpo.gov/fdsys/pkg/FR-2017-01-19/pdf/2017-01235.pdf>



POST MARCH 21, 2017

For submissions made on or after March 21, 2017, all non-exempt CBI claims must be substantiated at the time the information claimed as CBI is submitted to EPA

POST MARCH 21, 2017 (CONT.)

- A filing with a non-exempt CBI claim that is submitted without a substantiation will be considered deficient and EPA will send a notice of deficiency to the business. The notice will inform the business that:
 - Substantiations must be submitted within 30 calendar days in order to remedy its deficient CBI claim
 - Failure to provide substantiation(s) will be viewed as withdrawn CBI claim(s), and the information may be made public with no further notice

Access the source: <https://www.epa.gov/tsca-cbi/substantiating-cbi-claims-under-tsca-time-initial-submission#aftermarch20>



PRE MARCH 21, 2017

- Those submissions containing information claimed as CBI filed between June 22, 2016, and March 21, 2017, must be amended to provide a substantiation for all non-exempt information claimed as CBI
- Submitters have until September 19, 2017, to provide substantiations to the Agency for those claims that were not previously substantiated, primarily CDR and Section 5 filers

PRE MARCH 21, 2017 (CONT.)

- After September 19, 2017, EPA will notify the business of unsubstantiated CBI claims and the business will have 30 days to provide a substantiation of the claims
- Failure to provide substantiation(s) will be viewed as withdrawn CBI claim(s), and the information may be made public with no further notice to the business

HOW TO SUBSTANTIATE

- In order for EPA to make a determination regarding the validity of a CBI claim in a TSCA submission, information regarding the basis for the CBI claim (i.e. substantiation) must be provided
- EPA has developed substantiation templates that may be used as a starting point in preparing CBI substantiations
- Submitters are encouraged to use these substantiation template documents, but are not required to do so

HOW TO SUBSTANTIATE (CONT.)

- The purpose of the questions are to elicit facts that will help the Agency understand the basis for the submitter's belief that a particular data element claimed as CBI is in fact entitled to this status.
- Submitters may provide to EPA any information they believe supports the validity of their CBI claims
- Generalized or conclusory statements will be given little or no weight in EPA's determination on the confidentiality of the information

Access the source (including templates):

<https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations>

INFORMATION POTENTIALLY EXEMPT FROM SUBSTANTIATION

TSCA section 14(c)(2) Information generally not subject to substantiation requirements

Subject to subsection (f), the following information shall not be subject to substantiation requirements under paragraph (3):

- (A) Specific information describing the processes used in manufacture or processing of a chemical substance, mixture, or article
- (B) Marketing and sales information
- (C) Information identifying a supplier or customer
- (D) In the case of a mixture, details of the full composition of the mixture and the respective percentages of constituents

INFORMATION POTENTIALLY EXEMPT FROM SUBSTANTIATION

TSCA Section (c)(2) (cont.)

(E) Specific information regarding the use, function, or application of a chemical substance or mixture in a process, mixture, or article

(F) Specific production or import volumes of the manufacturer or processor

(G) Prior to the date on which a chemical substance is first offered for commercial distribution, the specific chemical identity of the chemical substance... if the specific chemical identity was claimed as confidential at the time it was submitted in a notice under section 2604 of this title

Access the source: <https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations#informationexempt>

SUBSTANTIATION CONSIDERATIONS FOR PMNs

Common Issues

- Everything claimed as CBI but substantiation does not address all those claims
- Health and safety data claimed as CBI without sufficient facts that substantiate the CBI claim
 - Note limitations of TSCA section 14(b) on CBI claims in health and safety studies.
- Assertions without facts to support them
- Confusion around exemptions.
 - The Agency may not believe the data elements are exempt, though they may be valid CBI claims if appropriately substantiated. Refer to TSCA section 14(c)(2).

Access the source: <https://www.epa.gov/tsc-cbi/what-include-cbi-substantiations#pmnform>



SUBSTANTIATION CONSIDERATIONS FOR CDR

Common Issues

- Company/site issue: Company claimed as CBI but site is not, and site contains company name
- Everything claimed as CBI but substantiation does not support all those claims
- Data elements claimed as CBI but information is publicly available
 - Chemical name in public documents where the chemical is offered for distribution in US commerce.
- Insufficient substantiations
 - For example: CDR Substantiation. II.D. Is the chemical substance known to be in US commerce?
(If you answered yes, please explain why the information should be treated as confidential.) Situation: Chemical is known to be offered for distribution in commerce as an R&D substance.)
- Assertions without fact to support them

Access the source: <https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations#cdr>

GENERAL SUBSTANTIATION CONSIDERATIONS

Common Issues

- Everything claimed as CBI but substantiation does not support all of the claims
- Health and safety data claimed as CBI without sufficient facts to substantiate the CBI claim
 - Note the limitations of TSCA section 14(b) on CBI claims in health and safety studies
- Assertions without any supporting facts
- Confusion around exemptions
 - The Agency may not believe the data elements are exempt, though they may be valid CBI claims if appropriately substantiated. Refer to TSCA section 14(c)(2).

Access the source: <https://www.epa.gov/tsca-cbi/what-include-cbi-substantiations#substantiationtemplates>

DEMONSTRATION

DEMONSTRATION



QUESTIONS?

- For further information or questions contact:
 - Scott Sherlock (202)564-8257
 - Jessica Barkas (202)250-8880
 - Brandon Mullings (202)564-4826
- For help with issues relating to electronic reporting, please contact:
 - CDX Help Desk at 1-888-890-1995