

PRE-PUBLICATION NOTICE

On July 10, 2019, Alexandra Dapolito Dunn, the EPA Assistant Administrator for Chemical Safety and Pollution Prevention, signed the following document:

Action: Notice.

Title: **Statutory Requirements for Substantiation of Confidential Business Information (CBI) Claims under the Toxic Substances Control Act (TSCA)**

FRL #: 9993-86

Docket ID #: EPA-HQ-OPPT-2017-0026

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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0026; FRL 9993-96]

Statutory Requirements for Substantiation of Confidential Business Information (CBI)

Claims under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: On January 19, 2017, EPA announced an interpretation of section 14 of the Toxic Substances Control Act (TSCA). Under this interpretation, non-exempt confidential business information (CBI) claims must be substantiated at the time the information claimed as CBI is submitted to EPA, and non-exempt CBI claims submitted without a substantiation are considered deficient. To facilitate compliance with the change in interpretation, EPA announced it would undertake a non-statutorily required practice of sending a notice of deficiency to an affected business that submitted a non-exempt CBI claim without a substantiation, providing an opportunity to correct the deficiency. The Agency also sent out notices of deficiency in instances where there were other procedural flaws in the submission, namely where the required CBI certification statement was not provided, or no generic name was provided when specific chemical identity was claimed as CBI. EPA's extensive outreach on this interpretation over the past two years has been effective. As such, EPA is announcing it is revising its policy and that it will cease sending these non-statutorily required notices of deficiency to businesses who submit procedurally flawed CBI claims. This action makes more efficient EPA's implementation of the TSCA section 14(g) requirement to review within 90 days of receipt all CBI claims for chemical identity, with limited exceptions, as well as to review a representative subset of at least 25% of

other non-exempt claims.

FOR FURTHER INFORMATION CONTACT: *For general information contact:* Colby

Lintner, Regulatory Coordinator, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 554-1404; e-mail address: *TSCA-Hotline@epa.gov*.

For technical information contact: Scott M. Sherlock, Attorney Advisor, Environmental Assistance Division, Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; telephone number: (202) 564-8257; e-mail address: *sherlock.scott@epa.gov*.

DATES: This action is effective on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

This announcement is directed to the public in general. It may be of particular interest to businesses that manufacture (defined by statute to include import) and/or process chemicals covered by TSCA (15 U.S.C. 2601 *et seq.*). This may include businesses identified by the North American Industrial Classification System (NAICS) codes 325 and 32411. Because this action is directed to the general public and other entities also may be interested, the Agency has not attempted to describe all of the specific entities that may be interested in this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Information?

1. *Docket.* EPA has established a docket for this action under docket identification number EPA-HQ-OPPT-2017-0026. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., CBI or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, will be available publicly only in hard copy. Publicly available docket materials may be found electronically at <http://www.regulations.gov>, or, if only available in hard copy, at the OPPT Docket. The OPPT Docket is located in the EPA Docket Center (EPA/DC) at Rm. 3334, EPA West Bldg., 1301 Constitution Ave., NW., Washington, DC. The EPA/DC Public Reading Room hours of operation are 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number of the EPA/DC Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Docket visitors are required to show photographic identification, pass through a metal detector, and sign the EPA visitor log. All visitor bags are processed through an X-ray machine and subject to search. Visitors will be provided an EPA/DC badge that must be visible at all times in the building and returned upon departure.

2. *Other related information.* For information about EPA's programs to evaluate new and existing chemicals and their potential risks and the amended TSCA, go to <https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/frank-r-lautenberg-chemical-safety-21st-century-act>.

II. What Action is the Agency Taking?

On June 22, 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act, which amended TSCA, was signed into law. The amended TSCA provides new requirements

relating to the assertion, substantiation, and review of CBI claims. On January 19, 2017, EPA published an interpretation of TSCA section 14(c)(3), indicating that the provision requires substantiation of all TSCA CBI claims at the time the information claimed as CBI is submitted to EPA, except for claims for information that are exempt from substantiation requirements by virtue of TSCA section 14(c)(2), (82 FR 6522, FRL-9958-34). This statutory interpretation was announced as effective within two months.

To give time for submitters to adjust to the new requirements, EPA announced that it would send a notice of deficiency to an affected business that submitted non-exempt CBI claims without substantiation on or after March 20, 2017, providing 30 days to submit the required substantiation. EPA also indicated on its website that it would send out notices of deficiency when there were other procedural flaws related to the CBI claims in a submission, including a failure to provide either a certification statement as required under TSCA section 14(c)(1)(B) and (c)(5), or a generic name required under TSCA section 14(c)(1)(C) when specific chemical identity is claimed as confidential. If the procedural flaws were not addressed within 30 days of receipt of the notice, then the CBI claims would be considered withdrawn and the information could be made public with no further notice.

Since the publication of the announcement the EPA has engaged in a variety of communications and outreach activities to educate the interested public on the interpretation. The EPA has facilitated or participated in webinars, and meetings with members of the public. EPA has also engaged via telephone with TSCA submitters, trade groups, and others on the requirements of TSCA section 14. EPA has also updated its webpages on CBI, to provide detailed guidance to facilitate compliance with the new requirements of TSCA. EPA has notified interested persons of the webpage updates via listserv communications. The communications and

outreach have been effective: since the March 21, 2017 effective date of the interpretation, EPA has sent out 984 notices of deficiency, the vast majority which relate to submissions received before March 21, 2017. Only 97 notices have been generated, to date, that related to filings directed to EPA after March 21, 2017.

Over two years have passed since the announcement of the section 14(c)(3) interpretation, so the interpretation is no longer new, and companies have had ample notice of the requirements. Therefore, EPA is phasing out the practice of sending notices of deficiency. This action makes more efficient EPA's implementation of the TSCA section 14(g) requirement to review within 90 days of receipt all CBI claims for chemical identity, with limited exceptions, as well as to review a representative subset of at least 25% of other non-exempt claims.

III. What is the Agency's Authority for Taking this Action?

TSCA section 14(c)(3), 15 U.S.C. 2613(c)(3), requires an affected business to substantiate all TSCA CBI claims at the time the affected business asserts the claim to EPA, except for information subject to TSCA section 14(c)(2).

TSCA section 14(c)(1)(a) requires an affected business to assert a claim for protection from disclosure concurrent with submission of the information in accordance with existing or future EPA rules.

TSCA imposes no requirement to provide notices of deficiency to affected businesses. EPA chose to do so to facilitate compliance with the statutory requirement.

IV. Implementation

Beginning on [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE *FEDERAL REGISTER*], EPA will no longer send out notices of deficiency in instances where submissions containing non-exempt information claimed as CBI do not include

substantiation for all such claims, and where the CBI claims have other procedural flaws such as a missing certification statement or, in the case of specific chemical identity CBI claims, a missing generic name. Instead, the Agency will provide written notice to affected business submitters that those CBI claims are invalid, and the underlying information is treated as not subject to a confidentiality claim, and therefore subject to disclosure without further notice.

This action is consistent with the Agency's overall efforts to be more efficient in the implementation of TSCA section 14 requirements. EPA will continue to assist submitters with compliance with TSCA section 14(c)(3) and has revised its webpages at <https://www.epa.gov/tsca-cbi> to include additional information on this policy, the substantiation questions from 40 CFR 2.204(e), suggested substantiation templates, substantiation exemptions and how the substantiations should be directed to the Agency.

Authority: 15 U.S.C. 2601 *et seq.*

Dated: July 10, 2019.

Alexandra Dapolito Dunn,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.