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ENVIRONMENTAL PROTECTION AGENCY

[EPA-HQ-OPPT-2017-0026; FRL-9958-34]

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: In June 2016, the Frank R. Lautenberg Chemical Safety for the 21st Century Act amended the Toxic Substances Control Act (TSCA). EPA is announcing an interpretation of TSCA section 14 concerning confidential business information (CBI) claims for information submitted to EPA. EPA interprets the revised 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.

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 60 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, however, be of particular interest to you if you 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 may also be interested, the Agency has not attempted to describe all 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 (ID) 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 publicly available only in hard copy. Publicly available docket materials are available 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?

The amended TSCA provides new requirements relating to the assertion, substantiation and review of CBI claims. EPA is interpreting the revised TSCA section 14(c)(3) as requiring substantiation of all CBI claims at the time the information claimed as CBI is submitted to EPA, except for claims for information subject to TSCA section 14(c)(2).

This action facilitates the Agency's implementation of TSCA section 14(g) to review all CBI claims for chemical identity, with limited exceptions, as well as to review a representative sample of at least 25% of other non-exempt claims.

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

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

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 rules. TSCA section 14(c)(3) in turn requires an affected business submitting a claim to protect information from disclosure to substantiate the claim, also in accordance with existing or future rules. The language of TSCA section 14(c)(3) is as follows:

“(3) Substantiation requirements. Except as provided in paragraph (2), a person asserting a claim to protect information from disclosure under this section shall substantiate the claim, in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section.”

EPA interprets TSCA section 14(c)(3) to require substantiation for all TSCA CBI claims, except for information within TSCA section 14(c)(2). That is the clear import of the language, “a person asserting a claim to protect information from disclosure under this section shall substantiate the claim. . .” While the final clause requires that submissions be in accordance with EPA rules, EPA interprets this provision as addressing the form and manner of a submission, not as making the substantiation requirement conditional upon a future EPA rulemaking. In the future, EPA may promulgate regulations governing the form and manner of substantiating CBI claims for those submissions addressed by this action. Nonetheless, EPA considers the statutory substantiation requirement to be in place as of the effective date of this action.

EPA’s interpretation is supported by legislative history for the recent amendments to TSCA. Both the Senate and House intended to require substantiation of CBI claims. See S. Rpt. 114-67 (observing, on page 5, that “section 14 [of pre-amendment TSCA] and EPA’s implementation of it has been criticized for failing to require. . . up-front substantiation of confidentiality claims,” and, on page 22, stating that, under the Senate bill, “all new claims for protection of information not

presumed to be protected from disclosure must be substantiated by the claimant”); H. Rpt. 114-176 at 29 (a confidentiality claim must “include. . . a justification for each claim of confidentiality”); Senate Environment and Public Works Committee summary: “Reforming the Toxic Substances Control Act” at 3 (http://www.epw.senate.gov/public/_cache/files/aa2ac4d1-15bb-4e71-9588-909d49bdcff2/tsca-reform-marketing-packet-5.19-final.pdf). (“The legislation promotes additional transparency by requiring up-front substantiation of claims to protect confidential commercial information. . . .”) EPA’s interpretation also is supported by TSCA section 14(i)(2), which provides that, “nothing in this chapter” prevents EPA from requiring substantiation before the effective date of rules that may be promulgated after June 22, 2016, the date on which the amendments to TSCA were enacted.

It might be maintained that TSCA section 14(c)(3) does not impose a substantiation requirement, but merely authorizes EPA to promulgate rules requiring substantiation. Alternatively, it might be maintained that the section does impose a substantiation requirement, but that the requirement must be effectuated through EPA rulemaking.

The first reading does not effectuate the legislative intent to require substantiation. In addition, the provision is not worded as a mere grant of authority. Numerous other provisions of TSCA – both of the pre-amended statute and of the Lautenberg amendments – demonstrate that Congress used more straightforward language when it intended simply to grant EPA rulemaking or other authority (e.g., TSCA section 14(f)(1) (“The Administrator may require any person. . . to reassert and substantiate or re-substantiate” an existing claim under certain circumstances); TSCA section 4(a)(2) (“The Administrator may, by rule, order, or consent agreement. . . require the development of new information”). Finally, TSCA section 14(c)(1) already authorizes EPA to promulgate rules governing the assertion of CBI claims. This paragraph provides authority for EPA to promulgate rules requiring

substantiation, and EPA in fact promulgated a number of rules requiring substantiation under similarly worded authority in pre-amendment TSCA section 14(c)(1). See, e.g., 40 CFR 711.30(b)(1), requiring up-front substantiation for chemical identity claims for Chemical Data Reporting under part 711. To interpret TSCA section 14(c)(3) as merely providing authority to require substantiation, where that authority already exists in TSCA section 14(c)(1), would arguably give TSCA section 14(c)(3) no effect at all.

The second reading amounts to a revision of the legislative text. TSCA section 14(c)(3) does not require EPA to undertake rulemaking; it merely acknowledges that EPA “may” do so. Unless this “may” were read as “shall”, EPA would be under no obligation to promulgate the rules required to carry out the objective of requiring substantiation. Here again, numerous other provisions of TSCA demonstrate that Congress used clear language – and included deadlines -- when it intended to require EPA to promulgate regulations (e.g., TSCA section 6(b)(1)(A)(“Not later than 1 year after June 22, 2016, the Administrator shall establish, by rule, a risk-based screening process. . . .”).

Having determined that TSCA section 14(c)(3) requires substantiation of all non-exempt TSCA CBI claims, EPA believes the provision is best interpreted as requiring substantiation *concurrent with the submission*. This is the natural reading of the requirement that “a person asserting a claim. . . shall substantiate the claim.” By analogy, TSCA section 14(c)(5) – another requirement newly added by the Lautenberg amendments – provides that a claimant “shall certify that the statement required to assert a [confidentiality] claim. . . and any information required to substantiate a claim. . . are true and correct.” While this provision does not explicitly state that the certification must accompany the submission, it is reasonable to conclude that Congress intended that result. Moreover, a requirement to substantiate CBI claims at some unspecified time would not create any meaningful self-executing requirement, because there would be no point in time at

which an affected business could be found not to have complied.

Reading the law as requiring substantiation concurrent with the CBI claim also comports with the legislative history. In addition to the history cited earlier in this document, the Senate Report, on p. 5, noted stakeholder concerns that, under pre-amendment TSCA, the lack of a requirement for up-front substantiation resulted in “an over-abundance of CBI claims, some of which may not be legitimate.” Interpreting TSCA section 14(c)(3) as requiring substantiation of a CBI claim concurrent with the claim’s submission best effectuates the expressed intent of Congress.

This interpretation is consistent with the requirement in TSCA section 14(g)(1) that EPA review most confidentiality claims for chemical identity and at least 25% of claims for other types of non-exempt information within 90 days after the receipt of the claim. An approach under which substantiations were submitted at some point after assertion of CBI claims would significantly reduce (and has already significantly reduced) the short period for such CBI reviews. To date, for each review, the Agency must contact each affected business, request the submission of a substantiation, and allow a period of time for the affected business to submit the substantiation. Since timely substantiation provides critical information for completing CBI reviews, it is reasonable to conclude that Congress intended for claims to be substantiated at the time the CBI claim is asserted.

When the amendments to TSCA became law on June 22, 2016, EPA published initial Questions and Answers (Q and A’s) in an effort to respond to the inquiries and requests concerning EPA’s views on the new law. EPA needed to issue guidance to the public as quickly as possible on a broad range of matters under the amendments, since the amendments became effective upon signature. In the Q and A’s on TSCA section 14, EPA stated that the Agency was using existing authorities to obtain CBI substantiations and that the Agency may revise CBI substantiation

requirements for specific types of information submissions by subsequent rulemaking. Since the time the Q and A's were developed, EPA has heard the views of a number of stakeholders and has had the opportunity to more fully review the statute and legislative history and to evaluate the operational considerations associated with the interpretation of TSCA section 14(c)(3).

Operationally, given the large volume of CBI claims, including those that the Agency has already received and those that the Agency expects to receive in the future, it is administratively efficient to interpret the statute as requiring up-front substantiation, which necessarily saves the Agency the time and resources that would otherwise be spent in attempting to contact the affected business. Up-front substantiation will also significantly enhance EPA's ability to meet the review deadlines in TSCA section 14(g). Further, requiring substantiation concurrent with submission will mitigate any need for an affected business to request an extension to substantiate a CBI claim. Additionally, requiring the affected business to provide justification at the time of submission may help limit unwarranted claims of CBI. Based on this further review, for the reasons stated above, EPA has concluded that the provision is best read as creating a requirement to substantiate non-exempt TSCA CBI claims concurrent with their submission.

IV. Implementation

Existing EPA confidentiality rules at 40 CFR part 2, section 2.204(e), provide substantiation questions that the Agency may specifically request answers to, pursuant to the procedures in those regulations. While those specific questions are not dictated by the self-executing substantiation requirement in TSCA section 14(c)(3), EPA suggests that companies look to those questions for guidance as to how to fulfill the TSCA section 14(c)(3) substantiation requirement for information that is not currently subject to an existing regulatory up-front substantiation requirement. The answers to those questions typically form the basis of EPA final confidentiality determinations, and

substantiations that do not address those questions might not provide sufficient information to uphold a determination, pursuant to TSCA section 14(g)(1), that information claimed as CBI is eligible for confidential protection. For information that is currently subject to a regulatory up-front substantiation requirement (for example, chemical identity CBI claims in the Chemical Data Reporting rule, under 40 CFR 711.30), the terms of that requirement, including the substantiation questions required, will continue to govern the substantiation.

EPA has revised its webpages on CBI to assist compliance with this interpretation of TSCA section 14. The webpages list the substantiation questions from 40 CFR 2.204(e) and provide information on substantiation exemptions and on how the substantiations should be directed to the Agency.

Because EPA is providing this interpretation of TSCA section 14(c)(3) for the first time in this document, the Agency is setting different procedures for those who have submitted or will submit information claimed as CBI under TSCA before the effective date of this action, i.e., [*INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER***], and those who submit information claimed as CBI afterwards.

*A. TSCA Submissions Filed on or after [*INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER***].*

Those submissions containing information claimed as CBI filed on or after the effective-date of this action (i.e., [*INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER***]) must provide a substantiation for all information claimed as confidential, other than information exempt from substantiation pursuant to TSCA section 14(c)(2). Any non-exempt CBI claim that is submitted without a substantiation will be considered deficient, and EPA will send a notice of deficiency to the affected business. The notice will inform the affected business that it must submit

its substantiation within 30 calendar days in order to remedy its deficient CBI claim. The notice letter will also inform the affected business that if a timely substantiation has not been received by EPA within 30 days of receipt of the letter, then any CBI claims not substantiated will be considered withdrawn, and the information may be made public with no further notice to the affected business.

*B. TSCA Submissions Filed Between June 22, 2016 and [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].*

Those submissions containing information claimed as CBI filed between June 22, 2016 and [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**], must provide a substantiation for all information claimed as confidential, other than information exempt from substantiation pursuant to TSCA section 14(c)(2). The Agency is giving submitters until [INSERT DATE 240 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] to provide substantiations and direct them to the Agency. If a substantiation has already been provided to EPA with the submission or in response to a substantiation request, no additional substantiation need be filed for the same information. Be aware, however, that if some non-exempt information claimed as confidential in a particular submission has already been substantiated and some has not, the unsubstantiated information claimed as CBI in the submission must still be substantiated by [INSERT DATE 240 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]. The CBI claims, and the substantiations, may then be reviewed consistent with the provisions of TSCA, its implementing regulations and in accordance with the Agency procedures set forth in 40 CFR part 2. Once [INSERT DATE 240 DAYS AFTER THE DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] has passed, if no substantiation has been received for a claim, then EPA will provide the affected business 30 days' notice and a final opportunity to substantiate. The notice will inform the affected business that any

CBI claims not substantiated at the end of the 30 days will be considered withdrawn, and the information may be made public with no further notice to the affected business.

EPA's electronic reporting systems for TSCA submissions have been modified to require substantiations for non-exempt CBI claims in submissions filed on or after *[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]*. Any new paper TSCA submissions that are directed to the Agency after that date must include substantiations for all non-exempt CBI claims at the time of submission.

For electronic submissions made using EPA's Central Data Exchange (CDX) during the period from June 22, 2016 to *[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]* that were not substantiated, affected businesses must provide substantiation for CBI claims using the amendment processes for the particular submission type. Information on electronic reporting, including how to make amendments, can be found at *<https://www.epa.gov/assessing-and-managing-chemicals-under-tsca/electronic-reporting-requirements-certain-information>*.

For any paper TSCA submissions that were submitted to the Agency during the period from June 22, 2016 to *[INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**]*, the affected business must submit substantiations for any non-exempt CBI claims that have not yet been substantiated. Submit these substantiations to:

TSCA Confidential Business Information Center (7407M)

WJC East; Room 6428; Attn: TSCA CBI Substantiations.

U.S. Environmental Protection Agency

1200 Pennsylvania Avenue, NW

Washington, DC 20460-0001

Courier Deliveries should be directed to:

U.S. EPA
Office of Pollution Prevention and Toxics

Confidential Business Information Center (CBIC)

Attn: TSCA CBI Substantiations

1201 Constitution Avenue, NW
WJC East; Room 6428
Washington, DC 20004-3302

(202) 564-8930

More information on how to substantiate CBI claims for paper submissions can be found at

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

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

Dated: January 13, 2017,

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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