Title 40 —Protection of Environment
Chapter I —Environmental Protection Agency
Subchapter R —Toxic Substances Control Act

PART 703—CONFIDENTIALITY CLAIMS

Authority: 15 U.S.C. 2613.

Source: 88 FR 37166, June 7, 2023, unless otherwise noted.

§ 703.1 Purpose and applicability.

(a) The purpose of this part is to describe procedures for asserting and maintaining confidentiality claims in accordance with TSCA section 14, and for EPA review of such claims. The procedures described in this part are generally applicable to the submission and EPA review of any TSCA submission, except to the extent that application of the requirements would be inconsistent with TSCA section 14(i). The procedures include requirements concerning the form and manner in which TSCA submissions must be made to meet requirements in TSCA sections 14(b) and (c), to facilitate EPA review of such claims in accordance with TSCA sections 14(f) and (g), and to facilitate disclosure of non-confidential information to the public in accordance with TSCA, FOIA, and their implementing regulations.

(b) This part applies to all information that is reported to or otherwise obtained by EPA pursuant to TSCA or its implementing regulations. This includes information that was first obtained by EPA other than pursuant to the authority of TSCA or its implementing regulations, provided that the following two criteria have been met:

(1) EPA has authority to collect the information under TSCA; and

(2) Either:

(i) Subsequent to its submission the information is being used to satisfy the obligation of a person under TSCA or its implementing regulations; or

(ii) EPA makes use of the information in the course of carrying out its responsibilities under TSCA (e.g., EPA considered such information in its actions under TSCA sections 4, 5, or 6).

(c)

(1) This part applies regardless of the following:

(i) Whether the information is intended by its submitter to be used by EPA in implementing TSCA;

(ii) Whether TSCA or an implementing regulation was cited as authority for the request or submission of the information; or

(iii) Whether the information was provided directly to EPA or through some third person.

(2) However, where such information is not protected from disclosure under TSCA Section 14, but the statute under which the information was originally provided to EPA limits disclosure for reasons other than business confidentiality (for example, limited disclosure of pesticide data to multinational pesticide producers under 7 U.S.C. 136h(g)), the disclosure limitation in the statute under which the information was obtained by EPA continues to apply, except where TSCA expressly requires disclosure of that information.

(d) The provisions of 40 CFR part 2, subpart B, apply to this section, as modified by 40 CFR 2.306.

§ 703.3 Definitions.

Link to an amendment published at 89 FR 102789, Dec. 18, 2024.

The definitions in this section and the definitions in TSCA section 3 apply to this part. In addition, the definition in § 720.3(ff) of this subchapter for *test data* also applies in this part.

Accept in the context of asserting a TSCA CBI claim means EPA's first approval of the submission containing the CBI claim in CISS, or its successor system.

Act, or *TSCA,* means the Toxic Substances Control Act, 15 U.S.C. 2601 *et seq.*

CDX or *Central Data Exchange* means EPA's centralized electronic document receiving system, or its successor system.

CISS or *Chemical Information Submission System* means EPA's web-based reporting tool for preparing and submitting TSCA submissions, or its successor system.

Confidentiality claim means a claim or allegation that business information is entitled to confidential treatment.

FOIA means the Freedom of Information Act, 5 U.S.C. 552, *et seq.*

Health and safety study has the same meaning as that provided in § 720.3(k) of this subchapter, except that for purposes of this part 703 the following information is not part of a health and safety study:

(1) The name, address, or other identifying information for the submitting company, including identification of the laboratory that conducted the study in cases where the laboratory is part of or closely affiliated with the submitting company.

(2) Internal product codes (*i.e.,* code names for the test substance used internally by the submitting company or to identify the test substance to the test laboratory).

(3) Names and contact details for testing laboratory personnel and names and other private information for health and safety study participants or persons involved in chemical incidents such as would typically be withheld under 5 U.S.C. 552(b)(6) or under other privacy laws.

(4) Information pertaining to test substance product development, advertising, or marketing plans, or to cost and other financial data.

§ 703.5 Requirements for asserting and maintaining confidentiality claims.

Any person who submits information under TSCA or these implementing regulations may assert a business confidentiality claim to information included in such submission except where such a claim is disallowed by applicable regulation under this subchapter. Such claim must be made concurrent with submission of the information. If no such claim accompanies the submission, EPA will not recognize a confidentiality claim, and the information in or referred to in that submission may be made available to the public (e.g., by publication of specific chemical name and CASRN on the public portion of the TSCA Inventory) without further notice.

(a) ***Supporting statement and certification.***

(1) A person asserting a confidentiality claim must submit a statement that the person has:

(i) Taken reasonable measures to protect the confidentiality of the information;

(ii) Determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;

(iii) A reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person; and

(iv) A reasonable basis to believe that the information is not readily discoverable through reverse engineering.

(2) The person must also certify that these four statements and any information required to substantiate the confidentiality claim in accordance with paragraph (b) of this section are true and correct.

(b) ***Substantiation.***

(1) Confidentiality claims must be substantiated at the time of submission to EPA, unless exempt under paragraph (b)(5) of this section. In the case of information collected by EPA or on behalf of EPA in person at the site of a TSCA inspection under section 11 of the Act, the affected company must assert its confidentiality claim(s) in writing at the time the information is collected, and then must provide substantiation of its confidentiality claims and the supporting statement and certification described in paragraph (a) of this section within ten business days after the inspection ends. Confidentiality claims lacking required substantiation after ten business days will be treated as deficient under paragraph (e) of this section. Unless otherwise directed by EPA, such information or materials must be submitted via CDX. In the case of an unusually voluminous document collection under section 11 of the Act, the affected company may request additional time to assert claims and provide substantiation, which EPA may grant at its discretion. The inspection is considered to have ended when the inspector physically exits the regulated facility on the last day of the inspection.

(2) Information in substantiations may be claimed as confidential. Such claims must be accompanied by the certification described in paragraph (a) of this section but need not be themselves separately substantiated.

(3) Substantiation questions for all claims. Unless otherwise specified elsewhere in this subchapter (e.g., 40 CFR part 711), answers to the following questions must be provided for each confidentiality claim in a TSCA submission:

(i) Please specifically explain what harm to the competitive position of your business would be likely to result from the release of the information claimed as confidential. How would that harm be *substantial*? Why is the substantial harm to your competitive position *likely* (*i.e.,* probable) to be caused by release of the information rather than just *possible*? If you claimed multiple types of information to be confidential (e.g., site information, exposure information, environmental release information, etc.), explain how disclosure of each type of information would be likely to cause substantial harm to the competitive position of your business.

(ii) Has your business taken precautions to protect the confidentiality of the disclosed information? If yes, please explain and identify the specific measures, including but not limited to internal controls, that your business has taken to protect the information claimed as confidential. If the same or similar information was previously reported to EPA as non-confidential (such as in an earlier version of this submission), please explain the circumstances of that prior submission and reasons for believing the information is nonetheless still confidential.

(iii)

(A) Is any of the information claimed as confidential required to be publicly disclosed under any other Federal law? If yes, please explain.

(B) Does any of the information claimed as confidential otherwise appear in any public documents, including (but not limited to) safety data sheets; advertising or promotional material; professional or trade publications; State, local, or Federal agency files; or any other media or publications available to the general public? If yes, please explain why the information should be treated as confidential. If this chemical is patented and the patent reveals the information you are claiming confidential, please explain your reasons for believing the information is nonetheless still confidential.

(iv) Is the claim of confidentiality intended to last less than 10 years (see TSCA section 14(e)(1)(B))? If yes, please indicate the number of years (between 1 and 10 years) or the specific date after which the claim is withdrawn.

(v) Has EPA, another Federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If yes, please provide the circumstances associated with the prior determination, whether or not the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(4) Additional substantiation questions for chemical identity-related claims only. Unless otherwise specified in the relevant electronic reporting form, answers to the following questions must be provided for each chemical identity-related confidentiality claim in a TSCA submission:

(i) Is this chemical substance publicly known (including by your competitors) to be in U.S. commerce? If yes, please explain why the specific chemical identity should still be afforded confidential status (e.g., the chemical substance is publicly known only as being distributed in commerce for research and development purposes, but no other information about the current commercial distribution of the chemical substance in the United States is publicly available). If no, please complete the certification statement:

> I certify that on the date referenced I searched the internet for the chemical substance identity (*i.e.,* by both chemical substance name and CASRN). I did not find a reference to this chemical substance and have no knowledge of public information that would indicate that the chemical is being manufactured or imported by anyone for a commercial purpose in the United States. [provide date].

(ii) Does this specific chemical substance leave the site of manufacture (including import) in any form, e.g., as a product, effluent, emission? If yes, please explain what measures have been taken to guard against the discovery of its identity.

(iii) If the chemical substance leaves the site in a form that is available to the public or your competitors, can the chemical identity be readily discovered by analysis of the substance (e.g., product, effluent, emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

(iv) Would disclosure of the specific chemical identity release confidential process information? If yes, please explain.

(5) Information described in paragraphs (b)(5)(i) and (ii) of this section is exempt from the requirement to substantiate the claim at the time of submission. EPA may identify on a reporting form certain information as exempt from substantiation. Additional assertions of exemption from substantiation may be asserted by the submitter. Each such assertion must include a detailed explanation for why the information falls within the claimed exemption. If the explanation is missing or inadequate, and the claim is not otherwise substantiated, EPA will place a hold on the submission, as described in paragraph (e) of this section.

(i) The following information types are exempt from the substantiation requirement at the time of information submission:

(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) Details of the full composition of a mixture and the respective percentages of constituents;

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

(F) Specific production or import volumes.

(ii) Exemption for chemical substances not yet offered for commercial distribution.

(A) A confidentiality claim for specific identity of a chemical substance, where the submission is made prior to the date on which the chemical substance whose identity is claimed as confidential is first offered for commercial distribution, is exempt from the requirement to substantiate confidentiality claims at the time of submission.

(B) A specific chemical identity claim includes specific chemical names, CAS numbers, molecular formulas, reactants (if required to be reported as part of the identification of the chemical, such as for Class 2 substances in § 720.45(a) of this subchapter), and structural diagrams; or in the case of microorganisms, genus and species name and genetic construct.

(C) This exemption applies where the submitter lacks information to reasonably conclude that the chemical substance has been offered for commercial distribution, where both:

(*1*) The chemical substance is not on the TSCA Inventory; and

(*2*) The substance is otherwise not publicly known to have been offered for commercial distribution.

(c) ***Public copies.*** All TSCA submissions and their accompanying attachments that include a confidentiality claim must be accompanied, at the time of submission, by a public version of the submission and any attachments, with all information that is claimed as confidential removed. In the case of documents collected by EPA or on behalf of EPA in person at the site of a TSCA inspection under section 11 of the Act, the affected company must provide such public copies at the same time and in the same manner as it provides substantiation of its confidentiality claims in accordance with paragraph (b)(1) of this section, within ten working days after the inspection ends. Only information that is claimed as confidential may be redacted or removed. Generally, a public copy that removes all or substantially all of the information would not meet the requirements of this paragraph (c) so will likely be treated as deficient under paragraph (e) of this section.

(1) Where the applicable reporting form or electronic reporting tool contains a checkbox or other means of designating with specificity what information is claimed as confidential, no further action by the submitter is required to satisfy this requirement.

(2) For all other information claimed as confidential, including but not limited to information in attachments and in substantiations required under paragraph (b) of this section, the submitter must prepare and attach a public copy. EPA may treat as deficient submissions with public copies that are entirely blank or that are substantially reduced in length as compared to the CBI version (*see* paragraph (e) of this section).

(d) ***Generic name.*** Each confidentiality claim for specific chemical identity must be accompanied by a structurally descriptive generic name for that substance. This generic name must be consistent with guidance on the determination of structurally descriptive generic names developed in accordance with, and made binding by, section 14(c)(4)(A) of the Act (e.g., *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA;* available at *https://www.epa.gov/tsca-inventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting*), and 15 U.S.C. 2613(c)(1)(C)(ii).

(1) At a minimum, the generic name must either:

(i) Be identical to the generic name for the same substance included on the non-confidential portion of the TSCA Inventory (if the substance is listed on the TSCA Inventory), or

(ii) For substances that are not listed on the TSCA Inventory, mask only the confidential portions of the specific chemical name. In most cases, only one structural element of a specific chemical name may be masked to protect a confidential chemical identity—if the submitter of a proposed generic name wishes to mask more than one such element, the submission must include an explanation of why masking only one element is insufficient to protect the confidential identity.

(2) Notwithstanding paragraph (d)(1) of this section, EPA may conclude that a generic name provided with the submission and listed on the current non-confidential version of the TSCA Inventory does not comply with 15 U.S.C. 2613(c)(1)(C). In such cases, EPA will notify the submitting company and proceed as described in paragraph (c)(4) of this section.

(3) A generic name that meets the requirements of section 14(c)(1)(C) of the Act prior to the date on which the chemical substance is first offered for commercial distribution for the purposes of a pre-market submission (e.g., a PMN) may not be sufficient for the purposes of subsequent listing on the TSCA Inventory, as identified upon review under section 14(g)(1)(C)(i) of the Act of a confidentiality claim for specific chemical identity made in a Notice of Commencement required under § 720.102 or § 725.190(f) of this subchapter. In such cases, EPA will notify the submitting company and proceed as described in § 720.102(f) or § 725.190(f) of this subchapter.

(4) If EPA concludes that the proposed generic name does not comply with 15 U.S.C. 2613(c)(1)(C), EPA will notify the submitter, and provide 10 business days for the submitter to provide a revised generic name. If EPA concludes that the revised generic name is still not acceptable, EPA will hold the submission for an additional period of up to 10 business days, proceeding as set out in paragraph (e) of this section.

(e) ***Deficient confidentiality claims.***

(1) A confidentiality claim under TSCA is deficient if it meets one or more of the following criteria:

(i) The confidentiality claim is not accompanied by the supporting statement and certification required by paragraph (a) of this section.

(ii) The confidentiality claim is not accompanied by the substantiation required by paragraph (b) of this section. If the submitter claims an exemption from substantiation under paragraph (b)(5) of this section and the exemption does not apply or an explanation is not provided for the exemption pursuant to paragraph (b)(5) of this section, the confidentiality claim is deficient.

(iii) The confidentiality claim is not accompanied by a public copy that meets the requirements of paragraph (c) of this section.

(iv) The confidentiality claim is for a specific chemical identity and is not accompanied by a generic name that meets the requirements of paragraph (d) of this section.

(2) A submission that is identified as deficient under paragraph (e)(1) of this section will be held for a period of up to 10 business days, and the submitter will be notified via CDX as described in paragraph (h) of this section. During the hold, which commences on the day the CDX notice is sent, any applicable review period for the underlying submission will be suspended until either the deficiency is corrected or the 10 business days elapse without such correction. Upon the occurrence of the first of either of these events, the applicable review period for the underlying submission commences or comes out of suspension. If the deficiency is not remedied during the suspension, EPA will proceed with review of the submission and may deny the CBI claim(s).

(f) ***Electronic reporting required.***

(1) TSCA submissions bearing confidentiality claims must be submitted via CDX, except where EPA directs that information subpoenaed under section 11(c) of the Act or materials collected or requested by EPA as part of an inspection under section 11(a) of the Act, not be submitted via CDX. Any required TSCA submission asserting a CBI claim that does not meet the requirements of this paragraph will be deemed incomplete. EPA reserves the ability to waive the requirements of this paragraph, at its discretion, where compliance is infeasible.

(2) You must use CISS to complete and submit TSCA submissions via CDX. To access CISS go to *https://cdx.epa.gov/* and follow the appropriate links.

(3) On receipt by EPA, each electronic TSCA submission will be assigned a case number or document identifier, which will be available to the submitter in their CDX account. This identifier may be used as a reference in future communications that concern the substance and may be used by EPA in public communications (e.g., FEDERAL REGISTER notices) that concern the submission, such as notices of receipt, final confidentiality determination, pending confidentiality claim expiration, or in other regulatory actions that concern the TSCA submission.

(g) ***Requirement to report health and safety studies using templates.*** Submitters of health and safety studies or information from such studies must provide such data in templated form, using an appropriate OECD harmonized template, if such template is available for the data type (*https://www.oecd.org/ehs/templates/*). Individual test or data submission rules or orders may specify an appropriate template or templates. Submission of templated data is not a substitute for submitting a full study report where a specific TSCA rule or order requires submission of the full study report (e.g., § 720.50(a) of this subchapter, or according to the terms of a specific order under section 5(e) of the Act).

(h) ***Requirement to maintain company contact information; electronic notices concerning confidentiality claims.***

(1) To facilitate ongoing or future communication concerning TSCA submissions, current contact information for all of the individuals associated with a particular TSCA submission must be maintained. Contact information for all the individuals associated with a particular TSCA submission must be updated by amending the submission via CDX, except that submissions that are either no longer accessible to the submitting company or that were not submitted via CDX (e.g., submissions that were originally provided on paper or other physical media), updated company contact must be provided via CDX using the appropriate EPA-provided electronic reporting application in CISS. In circumstances where ownership of the company or unit of a company has changed, such that contact information for one or more prior TSCA submissions that include confidentiality claims is affected, a notice of transfer of ownership must be directed to EPA via CDX. Instructions for providing this notice and for requesting access to copies of a prior TSCA submission are available at *https://cdx.epa.gov/*.

(2) When EPA contacts a TSCA submitter concerning confidentiality claims (e.g., related to a pending or concluded confidentiality claim review, a deficient submission, or in relation to the 10-year expiration of a confidentiality claim (described in section 14(e) of the Act)), EPA may provide notices and other correspondence to the submitter via CDX, using the contact information provided in the most recent version of the submission, or using the contact information provided in a more recent notice of transfer of ownership relating to that submission. The fact and date of delivery of such notice is verified automatically by CDX.

(3) In addition to individual notice described in paragraph (h)(2) of this section, EPA will publish on its website, or other appropriate platform, a list of TSCA submissions with confidentiality claims that are approaching the end of the ten-year period of protection described in section 14(e) of the Act. Such TSCA submissions will be referred to by the TSCA case or document identifier (as described in paragraph (f)(3) of this section) that was assigned to the submission by EPA when it was originally submitted. TSCA submissions will be added to this list at least 60 days prior to the end of the ten-year period of protection, along with instructions for reasserting and substantiating expiring claims.

(4) When a confidentiality claim is being reviewed pursuant to section 14(f) of the Act, EPA will provide, when necessary, notice of such review and an opportunity to substantiate or resubstantiate the affected confidentiality claim to the submitter using the contact information for the authorized official or technical contact provided in the most recent version of the submission or in a more recent notice of transfer of ownership relating to that submission.

(5) Where the submission with the relevant CBI claim was not originally made via CDX, EPA will send the notice via courier or US Mail to the company address provided in the most recent TSCA submission made by that company, or via other means that allows verification of the fact and date of receipt. The notice will provide instructions for substantiating claims that were exempt from substantiation when the confidentiality claim was asserted or for which the submitter was otherwise not required to provide substantiation at the time of initial submission, and for updating or re-substantiating as necessary any claims that were previously substantiated.

(i) ***Withdrawing confidentiality claims.*** TSCA confidentiality claims may be voluntarily withdrawn by the submitter at any time.

(1) Confidentiality claims in TSCA submissions that were originally made via electronic submission may be withdrawn. To withdraw a claim, a person must reopen the submission in CDX, remove confidentiality markings (e.g., confidential checkmarks or bracketing), revise public copies including any attachments to unredact the information no longer claimed confidential, and then resubmit the submission.

(2) For submissions that were not originally made via CDX, or that are no longer accessible to the submitting company via CDX, confidentiality claims may also be withdrawn via CDX using the “TSCA Communications” application or successor system. The withdrawal correspondence must indicate the case or document number (or other applicable document identifier or document identifying details) from which CBI claims are being withdrawn, identify the submitting company, and include a list or description of the information for which CBI claims are being withdrawn, including page numbers where relevant. Current contact information for the person withdrawing the claim must also be provided, in the event EPA needs clarification concerning which claim or claims are being withdrawn.

(j) ***Amending public copy following confidentiality claim denial or expiration.***

(1) Following the expiration or EPA's denial of a TSCA confidentiality claim, the person who asserted the denied or expired claim should prepare and submit a revised public copy of the submission to EPA, following the procedures for voluntarily withdrawing claims described in paragraph (i) of this section.

(2) If the person who asserted the denied or expired claim declines or fails to provide within 30 days a revised public copy of the submission that includes the information for which the confidentiality claim(s) were denied or expired, EPA may prepare an addendum to the original public copy, as needed, disclosing the information to the public.

§ 703.7 EPA review of confidentiality claims under TSCA section 14(g).

(a) ***Representative subset and selection of submissions for review.***

(1) A representative subset consists of at least 25 percent of confidentiality claims asserted under TSCA, not including claims for specific chemical identity or for the categories of information listed in section 14(c)(2) of the Act. Excluded from the representative subset are:

(i) Inquiries with respect to potential submission to EPA of a notification under 40 CFR part 720, 721, 723, or 725 by a person who has not submitted the notification at the time of the inquiry, including inquiries under § 720.25(b) or § 721.11 of this subchapter;

(ii) Submissions or other communication not submitted to EPA via CDX; and

(iii) Amendments to previous TSCA submissions.

(2) To satisfy its confidentiality claim review obligations under section 14(g)(1)(C)(ii) of the Act, EPA will generally review all claims (except those exempt from substantiation under section 14(c)(2) of the Act) in every fourth TSCA submission submitted via CDX that is part of the representative subset, in chronological order of receipt by EPA. For each submission selected for review as part of the representative subset, EPA reviews and approves or denies every individual confidentiality claim in that submission (except claims that are exempt under sections 14(c)(2) and 14(g) of the Act), including claims made in attachments and amendments available to EPA at the time of the review.

(b) ***Review of new and expiring confidentiality claims under TSCA Section 14(g).***

(1)

(i) Under section 14(g) of the Act, EPA will review:

(A) All chemical identity claims asserted in TSCA submissions except those that are exempt from substantiation according to section 14(c)(2)(G) of the Act; and

(B) a representative subset of other confidentiality claims as provided in paragraph (a) of this section.

(ii) Final determinations will be issued by the General Counsel or their designee, which may include personnel outside of the Office of General Counsel.

(2) EPA will review all timely requests for extension of claims under section 14(e) of the Act within 30 days of receipt.

(3) EPA will also review or re-review confidentiality claims under certain other circumstances, as set out in section 14(f) of the Act. Review under section 14(f) of the Act are conducted in accordance with procedures set out in § 703.8.

(c) ***Commencement of the review period and effect of amendments.*** Subject to § 703.5(e), the 90-day review period described in section 14(g) of the Act begins on the day that EPA accepts a new TSCA submission that includes confidentiality claims. For new information, other than specific chemical identity, added to a submission after EPA first accepts the submission, the review will take into account such amendments to that submission that are made either up to 60 days from the original submission date, or until the Agency issues a final confidentiality determination for the submission, whichever comes first. If a submission is amended to report an additional or different chemical substance that includes a new specific chemical identity claim, the TSCA section 14(g) review period for the added chemical identity begins on the day EPA accepts the amendment including the new claim.

(d) ***Publication of final determinations.*** Final confidentiality determinations will be published on EPA's website, or other platform, periodically, in accordance with the requirements of section 26(j) of the Act.

(e) ***Claim denials and notice period.*** In the case that EPA determines that a claim or part of a claim is not entitled to confidential treatment, EPA will provide notice of the denial to the person who made the claim and provide reasons for the denial or denial in part. The notice will be provided, as described in § 703.5(h). The 30-day notice period described in section 14(g)(2)(B) of the Act begins on the next business day following the date the notice is made available to the submitter in their CDX account.

(f) ***Substantive criteria for use in confidentiality determinations.*** Information claimed as confidential under section 14 of the Act will be approved if all of the following apply:

(1) The business has asserted a business confidentiality claim which has not expired by its terms, nor been waived nor withdrawn;

(2) The business has satisfactorily shown that it has taken reasonable measures to protect the confidentiality of the information, and that it intends to continue to take such measures for as long as the claim is maintained;

(3) The information is not, and has not been, reasonably obtainable without the business's consent by other persons (other than governmental bodies) by use of legitimate means (other than discovery based on a showing of special need in a judicial or quasi-judicial proceeding; e.g., the business has demonstrated a reasonable basis to believe the information is not readily discoverable through reverse engineering);

(4) The business has demonstrated a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the business; and

(5) No statute denies confidential protection to the information. Information from health and safety studies respecting any chemical that has been offered for commercial distribution or for which testing is required under section 4 of the Act or notice is required under section 5 of the Act is not entitled to confidential treatment, except that the following information may be entitled to confidential treatment if it otherwise meets the remainder of criteria in this paragraph (f):

(i) Any information, including formulas (including molecular structures) of a chemical substance or mixture, that discloses processes used in the manufacturing or processing of a chemical substance or mixture; or

(ii) In the case of a mixture, the portion of the mixture comprised by any of the chemical substances in the mixture.

(6) The business adequately demonstrates that the information is commercial or financial information obtained from a person and is confidential within the meaning of FOIA Exemption 4 (5 U.S.C. 552(b)(4)).

(g) ***Criteria to use in consideration of requests for extension under TSCA section 14(e).*** Requests to extend the period of confidentiality protection under TSCA section 14(e) will be evaluated using the same criteria as described in paragraph (f) of this section. Requests for extension may rely on a substantiation previously provided to EPA, but the submitter must recertify that the substantiation is still true and correct.

§ 703.8 EPA review of confidentiality claims under TSCA section 14(f).

(a) ***Review of confidentiality claims initiated under TSCA Section 14(f).*** In accordance with the procedures described in this section, EPA may review confidentiality claims where authorized by TSCA section 14(f)(1), and will review confidentiality claims subject to TSCA section 14(f)(2) in the following situations:

(1) In response to a request under the Freedom of Information Act (5 U.S.C. 552) for TSCA information claimed confidential;

(2) If EPA has reason to believe that information claimed confidential does not qualify for protection from disclosure; or

(3) For any chemical substance which EPA determines under TSCA section 6(b)(4)(A) presents an unreasonable risk of injury to health or the environment.

(b) ***Substantiation exemptions not applicable.*** The exemptions from substantiation requirements contained in section 14(c)(2) of TSCA do not apply to confidentiality claims reviewed under this section 703.8, even if such exemptions applied when the information was originally submitted to EPA.

(c) ***Additional substantiation.*** If necessary, such as where substantiation has not previously been provided for confidentiality claims under review, or where EPA has reason to believe the substantiation is incomplete or out of date, EPA will request additional substantiation from the person(s) that claimed the information as confidential.

(d) ***Additional substantiation notice.*** If additional substantiation is necessary, EPA will provide notice to the person that claimed the information as confidential in the manner specified in § 703.5(h)(4). The notice will provide the time allowed for additional substantiation from the business and the method for requesting a time extension if necessary. If the person does not make a timely response or extension request, EPA will consider any existing substantiations in its review of the claims or, in the case of any unsubstantiated claim, EPA will construe this as a waiver of the claim and may make the information public without any further notice to the submitter.

(e) ***Substantive criteria for use in confidentiality determinations.*** The criteria in § 703.7(f) apply to confidentiality determinations initiated under TSCA section 14(f).

(f) ***Adverse determinations and notice period.*** Final determinations will be issued by the General Counsel or their designee, including personnel outside of the Office of General Counsel. Except for instances where claims were waived, if EPA determines that information claimed confidential does not qualify for protection from disclosure, EPA will provide written notice to the person who asserted the claim. The notice will be provided electronically, as described in § 703.5(h)(2). The 30-day notice period described in TSCA section 14(g)(2)(B) begins on the next business day following the date the notice is made available to the submitter in their CDX account.

(g) ***Disclosure of Information.*** After a final determination has been made by EPA to release some or all of the information claimed as confidential, the Agency shall make the information available to the public (in the absence of a court order prohibiting disclosure) whenever:

(1) The period provided for commencement by a business of an action to obtain judicial review of the determination has expired without notice to EPA of commencement of such an action; or

(2) The court, in a timely-commenced action, has denied the person's motion for a preliminary injunction, or has otherwise upheld the EPA determination.

(h) ***Notice relating to public requests for records.*** Any person whose request for release of the information under 5 U.S.C. 552 is pending at the time notice is given under paragraph (f) of this section shall be furnished notice under 5 U.S.C. 552 either stating the circumstances under which the some or all of the information will be released or denying the request if all requested information was found to be entitled to confidential treatment.