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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 2, 702, 703, 704, 707, 716, 717, 720, 723, 725, and 790

[EPA-HQ-OPPT-2021-0419; FRL-8223-02-OCSPP]

RIN 2070-AK68

Confidential Business Information Claims Under the Toxic Substances Control Act (TSCA)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is finalizing new and amended requirements concerning the assertion and treatment of confidential business information (CBI) claims for information reported to or otherwise obtained by EPA under the Toxic Substances Control Act (TSCA). Amendments to TSCA in 2016 included many new provisions concerning the assertion, Agency review, and treatment of confidentiality claims. This document finalizes procedures for submitting such claims in TSCA submissions. It addresses issues such as substantiation requirements, exemptions, electronic reporting enhancements (including expanding electronic reporting requirements), maintenance or withdrawal of confidentiality claims, and provisions in current rules that are inconsistent with amended TSCA. The rule also addresses EPA procedures for reviewing and communicating with TSCA submitters about confidentiality claims.

DATES: This final rule is effective on August 7, 2023.

ADDRESSES: The docket for this action, identified under docket identification (ID) number EPA-HQ-OPPT-2021-0419, is available online at <https://www.regulations.gov> or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket) in the Environmental Protection Agency Docket Center (EPA/DC). Please review the visitor instructions and additional

information about the docket available at <https://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Jessica Barkas, Project Management and Operations Division (7401), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460-0001; telephone number: (202) 250-8880; email address: barkas.jessica@epa.gov.

For general information contact: The TSCA-Hotline, ABVI-Goodwill, 422 South Clinton Ave., Rochester, NY 14620; telephone number: (202) 554-1404; email address: TSCA-Hotline@epa.gov.

SUPPLEMENTARY INFORMATION:

I. Executive Summary

A. Does this action apply to me?

You may be affected by this action if you have submitted or expect to submit information to EPA under TSCA and have made or expect to make any confidentiality claims concerning that information. Persons who seek information on such submissions may also be affected by this action. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include:

- Manufacturers, importers, or processors of chemical substances (NAICS codes 325 and 324110), e.g., chemical manufacturing and petroleum refineries.

If you have any questions regarding the applicability of this action to a particular entity, consult the technical contact person listed under **FOR FURTHER INFORMATION CONTACT**.

B. What is the Agency's authority for taking this action?

The statutory authority for this action is provided by section 14 of TSCA, as amended (15 U.S.C. 2601 *et seq.*). TSCA section 14 (15 U.S.C. 2613) includes requirements for asserting confidentiality claims and for EPA review of such claims to determine whether the information is entitled to the requested protections. Section 14 includes provisions that explicitly contemplate promulgation of implementation rules by the Administrator. For example, TSCA section 14(c)(1)(A) requires persons seeking to protect information from disclosure to assert such a claim concurrent with submission of the information, "in accordance with such

rules regarding a claim for protection from disclosure as the Administrator has promulgated or may promulgate pursuant to this title." In addition, TSCA section 14(c)(3) requires that confidentiality claims be substantiated "in accordance with such rules as the Administrator has promulgated or may promulgate pursuant to this section." Other provisions in TSCA section 14 further recognize the role of the Administrator in specifying the form and manner in which the requirements of TSCA section 14 should be fulfilled (e.g., manner of submitting confidentiality claims, manner in which EPA will make required notices under TSCA sections 14(g) or 14(e)).

Discussion of additional authority to require electronic reporting under TSCA may be found in the preamble to the final rule entitled "Electronic Reporting under the Toxic Substances Control Act; Final Rule" (Ref. 1). In addition, the Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

C. What action is the Agency taking?

EPA is finalizing new and amended requirements concerning the assertion and treatment of CBI claims under TSCA, 15 U.S.C. 2601, *et seq.* The Frank R. Lautenberg Chemical Safety for the 21st Century Act of 2016, Public Law 114-182 (hereafter "the Lautenberg amendments"), made significant amendments to TSCA, including new provisions governing the assertion and review of CBI claims that EPA is implementing in this action.

In this document, EPA is finalizing specific procedures for submitting and supporting CBI claims under TSCA, including among other things: (1) substantiation requirements applicable at the time of submission; (2) electronic reporting requirements; (3) requirements to provide certification statements and generic names when making confidentiality claims; (4) treatment of information used for TSCA purposes that EPA has authority to require under TSCA but was originally submitted via other means; and (5) maintenance and withdrawal of confidentiality claims.

EPA is also finalizing specific procedures for reviewing and communicating with TSCA submitters about confidentiality claims, including requirements for submitters to maintain contact information, and procedures for EPA to provide notices to submitters concerning their claims.

EPA is finalizing new provisions, as well as amending and reorganizing

existing provisions concerning assertion of confidentiality claims under TSCA. Regulatory provisions concerning TSCA CBI claims are currently spread over several parts in the Code of Federal Regulations (CFR). EPA has general provisions regarding confidentiality claims at 40 CFR part 2, subpart B. Those general provisions are accompanied by sections pertaining to confidentiality for many of the statutes administered by the Agency. The TSCA-specific provisions of the Agency's general business confidentiality regulations are at 40 CFR 2.306. In addition, many of the specific TSCA regulations in 40 CFR contain their own provisions regarding CBI, such as in 40 CFR part 711 (Chemical Data Reporting) and 40 CFR part 720 (Premanufacture Notification).

In this final rule, most procedural requirements for asserting and maintaining confidentiality claims are organized in a new part of 40 CFR, *i.e.*, in part 703. The provisions in 40 CFR part 703 will apply to any TSCA submission, except as modified elsewhere by more specific provisions in 40 CFR part 2 or other TSCA-specific regulations in Title 40 of the CFR.

D. What are the estimated incremental economic impacts of this action?

EPA has evaluated the potential incremental impacts of this rulemaking, including alternative options. The details are presented in the economic analysis prepared for the rule (Ref. 2), which is available in the docket and is briefly summarized here. The benefits of the rule include improvements to EPA's management of CBI, specifically in cases of deficient claims, and improved communication and increased public transparency for chemical information. The rule is expected to decrease the frequency of submitter error and increase efficiency in the processes for asserting and maintaining CBI claims. Lastly, the rule will bring TSCA confidentiality regulations in line with the changes to TSCA section 14 brought about by the Lautenberg amendments.

EPA estimates that the public will incur a one-time burden and cost of approximately 2,945 hours with an associated cost of approximately \$272,804 in the first year after the rule is finalized and an annual, ongoing burden of approximately 523 hours with an associated cost of approximately \$45,529 in each following year.

II. Background

The Lautenberg amendments included several significant changes to TSCA section 14. These include requirements that persons submitting

information under TSCA substantiate most confidentiality claims at the time of submission, as well as additional statement, certification, and generic name requirements. Under TSCA section 14(e), in order to maintain most claims beyond a 10-year period, submitters are required to reassert and resubstantiate those claims before the end of that 10-year period.

Several new requirements also apply to EPA, including requirements in TSCA section 14(g) to review and approve or deny all chemical identity CBI claims asserted since the Lautenberg amendments were enacted concerning substances that are or have been offered for commercial distribution, as well as a subset of all other confidentiality claims. Such reviews must be completed within 90 days of assertion of the claim. Under TSCA sections 8 and 14, EPA must also review all confidentiality claims for the chemical identity of substances listed as active on the TSCA Inventory and assign and apply unique identifiers (UIDs) to substances with approved confidentiality claims for chemical identity. The amendments to TSCA section 14 also expanded the categories of people who may now access TSCA CBI. These new provisions have been discussed in previous documents published in the **Federal Register** (see *e.g.*, Refs. 3, 4, and 5).

Some TSCA regulations promulgated or amended since the Lautenberg amendments have included confidentiality provisions conforming to the amendments (*e.g.*, Chemical Data Reporting at 40 CFR 711.30 and Active/Inactive Inventory Reporting at 40 CFR 710.37). The final rule includes provisions intended to implement many of the new requirements in TSCA section 14 for the remaining TSCA regulations, especially requirements for asserting a CBI claim and procedures for EPA review of such claims. Further background information and a detailed explanation of the proposed rule is included in the preamble to the proposed rule (Ref. 6).

III. Summary of Response to Public Comments

In response to the proposed rule, EPA received eighteen public comments. The commenters include trade associations, non-governmental organizations, consultants, and individuals (two anonymous). Major comments are discussed in the context of particular provisions in Unit IV. A more detailed discussion is available in the Response to Comment Document for this rule, which is available in the docket (Ref. 8).

IV. Summary of the Final Rule

A. Existing Regulations Governing Confidentiality Under TSCA

The final rule centralizes most CBI-related procedures in a new part of the TSCA regulations, 40 CFR part 703. This new part also largely replaces TSCA-specific CBI regulations in 40 CFR 2.306, though a few provisions do remain regarding, *e.g.*, the applicability of the Agency's public information rules to TSCA CBI in general and procedures for disclosure of information under special circumstances described in TSCA sections 14(d)(2) through (7). Section 2.306 has been updated in some provisions to conform to the timeframes specified for notice under TSCA section 14(g).

In some cases, such as the regulations implementing TSCA section 14(d)(2) and (7), the final rule retains a notice requirement that is not required by TSCA but which has historically been a feature of EPA's 40 CFR part 2, subpart B, regulations. EPA received some comments about the proposal to retain these notice requirements in the rules, but notes that TSCA does not prohibit providing such notice and that especially in the case of rarely used disclosure provisions, providing notice to the person who asserted the CBI claim does not tend to significantly increase Agency burden or diminish the public availability of information. Providing notice would also tend to reduce confusion for the person who asserted the CBI claim and reduce the possibility of unnecessary conflict over the handling of the information.

B. Purpose and Applicability

EPA has somewhat revised 40 CFR 703.1 in response to public comment but retains the proposed provisions concerning the scope of information that is considered "reported to or otherwise obtained by EPA pursuant to TSCA or its implementing regulations," particularly that data need not have been submitted pursuant to an exercise of TSCA authority in order for it to be considered obtained under TSCA.

Some commenters criticized the scope provisions as greatly expanding the range of information considered submitted under TSCA, while others criticized the proposal as greatly narrowing this range. EPA responds to both groups of commenters that the proposal was not intended to modify the scope of TSCA jurisdiction, but rather to clarify it. EPA also notes that the provision regarding what is considered obtained under TSCA in the final rule works in tandem with the retention of disclosure limits (for reasons other than

business confidentiality) in the statute under which the information was originally provided to EPA.

EPA has modified the proposed regulation text in response to some of these comments. The final rule clarifies and reconciles the applicable provisions of TSCA and the other laws by which EPA may have received data that is later used for TSCA purposes. Even where TSCA excludes certain data from eligibility for business confidentiality protection, there are very limited circumstances where the statute requires affirmative disclosure of that same data by EPA. Instead, data used under TSCA might have originally been submitted under and remain protected or restricted from disclosure for reasons other than business confidentiality under another statute. An example is FIFRA section 10(g), which limits disclosure of certain pesticide data to persons who can certify they are not acting on behalf of an entity engaged in the production, sale, or distribution of pesticides in countries other than the United States. Where certain data is not entitled to business confidentiality protections under TSCA but *does* enjoy disclosure protections under another statute for other reasons (*e.g.*, FIFRA section 10(g)), EPA does not believe there is a conflict between the two statutory provisions. It therefore does not violate TSCA for EPA to withhold or restrict disclosure of such data pursuant to the requirements of the other law. EPA has therefore replaced the proposed language concerning resolution of conflicts with language clarifying that information that was originally submitted under a statute other than TSCA may be protected from disclosure under the provisions of the other statute for reasons other than claims of business confidentiality, even if the information is subsequently used under TSCA and would not be eligible for business confidentiality protections under TSCA.

Related to these provisions, some commenters were concerned that data originally obtained under other statutes would be used and potentially disclosed to the public by EPA without any notice to the original submitter. Particularly with respect to disclosure, this is not the case. Such data, once it is considered as being submitted or obtained under TSCA, will be treated and disclosed consistent with today's final rule, TSCA, and any other pertinent laws. For example, if the information were claimed as business confidential and became subject to a Freedom of Information Act (FOIA) request or EPA otherwise believed that the information might not be entitled to confidential

treatment, the Agency would review and make a final confidentiality determination under TSCA section 14(f), which would involve notice and opportunity for affected persons to substantiate confidentiality claims—if EPA denies the confidentiality claim, the affected persons would be provided notice according to today's final rule and TSCA section 14(g).

C. Definitions

EPA received several comments concerning the proposed definition of "health and safety study" at 40 CFR 703.3, particularly the proposed excluded categories of information. Some commenters proposed additional exclusions, while others argued that there should be fewer or no exclusions because having any exclusions is inconsistent with TSCA and/or that the proposed categories are information underlying and relevant to the studies.

In this final rule, EPA is declining to add exclusions beyond those originally proposed but is making modifications to the original proposal to combine similar exclusions and to clarify the intended scope of the exclusions. As EPA explained in the preamble to the proposed rule (Ref. 6), EPA considers some types of information that may be included in or with a study document as not part of the "health and safety study" as defined in TSCA section 3(8). That definition states that the term "health and safety study" means any study of any effect of a chemical substance or mixture on health or the environment or on both, including underlying information and epidemiological studies, studies of occupational exposure to a chemical substance or mixture, toxicological, clinical, and ecological studies of a chemical substance or mixture, and any test performed pursuant to this chapter. This definition does not seek to provide an exclusive list of what is or is not "included" in the health and safety study but instead clarifies that all "underlying" information must be considered part of the study. The term "underlying" is an adjective "used to describe something on which something else is based." Cambridge Dictionary (Online). A study report may contain information beyond that which is the basis for the study. Information such as the names of lab technicians neither form the basis for the study nor is it relevant to the study results.

EPA notes that most of the exclusions have long been part of the existing TSCA rules in one form or other, such as in 40 CFR parts 720 and 716, so the final rule will in most respects maintain the status quo. EPA also considered

TSCA section 14(b)(1) ("[i]nformation that is protected from disclosure under this section, and which is mixed with information that is not protected from disclosure under this section, does not lose its protection from disclosure notwithstanding that it is mixed with information that is not protected from disclosure") in finalizing the list, reasoning that the excluded types of information may be protected from disclosure under TSCA section 14 although included in a document that also contains information that is not protected from disclosure. EPA notes that study reports can and often are provided in a number of formats, with variable detail, and with varying levels and types of information that are ancillary to the study report.

EPA is declining to add additional exclusions, as many of the suggestions made were either redundant with the proposed list (*e.g.*, laboratory address is redundant with the name of the laboratory), or do not constitute information that EPA can categorically determine as unnecessary to interpret the study, and therefore cannot be categorically excluded from the definition of a health and safety study under TSCA section 3(8).

The final rule is modified from the proposal to combine similar exclusions and to clarify the intended scope of the exclusion. The exclusion for name of the submitting company (previously included in 40 CFR parts 716 and 720) is combined with the exclusion for name of laboratory. This exclusion is intended to permit confidentiality claims for submitting company identity and other information that would disclose company identity, such as addresses and laboratory name in the case that the laboratory that conducted the study was part of or closely related to the submitting company. The exclusion for "internal product codes" is clarified with a parenthetical that explains that this refers to the code names for a test substance that is used internally by the submitting company or is used to identify the test substance by the test laboratory. The exclusions for names of laboratory personnel and for names and other private information of study subjects are also combined in the final rule. Finally, the proposed exceptions for costs and other financial data and for product development, advertising, and marketing plans are combined. These types of information do not often appear in study reports themselves but may be included with a larger submission that includes a study report or other health and safety data or included in materials relating to cost

sharing for chemical testing (e.g., in relation to a test order).

D. Requirements for Asserting a Confidentiality Claim

TSCA section 14(c) governs assertion of confidentiality claims for TSCA submissions. This provision requires that persons submitting information under TSCA substantiate most confidentiality claims at the time of submission. It also includes additional certification and generic name requirements. The final rule retains most of the proposed provisions, with some modifications to clarify the regulatory provisions, or in response to public comment.

1. Assertion of Confidentiality Claim Upon Submission of Information to EPA

The final rule requires that confidentiality claims be asserted (and substantiated as necessary) at the time of submission (limited exceptions may apply in the case that such information is collected during an in-person TSCA enforcement inspection). See 40 CFR 703.5. This includes confidentiality claims for specific chemical identity, which must be asserted as specified in existing reporting rules (e.g., CDR, 40 CFR part 711). Several commenters expressed concern regarding language in the preamble to the proposed rule clarifying that failing to assert a CBI claim for a specific chemical identity submitted under those existing regulations would lead to the specific chemical identity being moved from the confidential to the public portion of the Inventory. (Refs. 6 and 8.) The commenters' concern pertains to those instances where the chemical identity is reported by accession number (a non-confidential identifier) and no chemical identity CBI claim is asserted, with the result that the specific chemical identity is moved to the public Inventory. Existing rules require that the reporter assert and substantiate confidentiality claims for the specific identity if they wish for that substance to remain on the confidential portion of the TSCA Inventory. See, e.g., 40 CFR 711.20(e). Commenters expressed concerns that downstream customers or processors of a specific chemical would report under TSCA by accession number and, ignorant of specific chemical identity, could accidentally or intentionally waive the confidentiality claim and cause the substance to lose confidential status.

EPA has consistently maintained and provided public notice of its position that if *any* submitting entity chooses not to assert and/or substantiate a confidentiality claim for a chemical

identity as required by TSCA section 14, the chemical identity is no longer entitled to confidential treatment and may be published on the public portion of the TSCA Inventory. For example, the Agency noted in the 2009 updates of the TSCA Inventory that “*some* manufacturers of these 530 chemical substances did not include any claim of confidentiality for the chemical identity of the chemical substance with the IUR submission.” (74 FR 37224 (July 28, 2009) (FRL–8392–4)) (emphasis added). See also TSCA Inventory Update Reporting Modifications; Chemical Reporting, (76 FR 50815 and 50825 (Sept. 15, 2011) (FRL 8872–9)) (stating that failure to identify the chemical identity as CBI and complete upfront substantiation will waive any CBI claim to the chemical identity). This position was further reinforced recently in the 2020 Procedures for Review of Confidential Business Information Claims for the Identity of Chemicals on TSCA Inventory’s Response to Comments (RTC) where EPA stated “[i]f another person reveals to the public that a confidential chemical substance is manufactured or processed for nonexempt commercial purposes in the United States, then the specific chemical identity would no longer be eligible for confidential protection, and CBI claims for that specific chemical identity would be denied upon review” (Ref. 10, at 17.)

EPA has considered the commenters' concerns that an entity lacking knowledge of a specific chemical identity may nonetheless waive confidentiality for that chemical identity. Such a situation might arise when TSCA reporting rules implicate a universe of reporters from sectors that typically have little knowledge of the identities of specific chemical substances in their products, one example being importers of articles containing the chemical substance in question. The Agency recognizes that this issue might arise in specific contexts. However, this final rule addresses a wide variety of situations where the knowledge issue is not presented. EPA believes that the best way to address commenters' concerns is to include measures in specific TSCA reporting rules that take into account the reporting entity's potential lack of knowledge, where such measures are necessary. Addressing the issue in the context of specific reporting rules will allow EPA to take into consideration the unique reporting context for the rule, such as the attributes of specific reporters. For example, a specific reporting rule might except all or a

category of reporters from requirements to reassert chemical identity claims to maintain confidential Inventory status.

Outside this final rule, the Agency has already begun exploring options for addressing the knowledge concerns raised by the commenters. For example, in the proposed rule TSCA section 8(a)(7) Reporting and Recordkeeping Requirements for the Perfluoroalkyl and Polyfluoroalkyl (PFAS) Substances; Notice of Data Availability and Request for Comment, the Agency sought to clarify and add language to the PFAS proposed rule based in part on comments received during the public comment period for today's final rule and concerning an entity's knowledge of a specific chemical identity (Ref. 11).

2. Substantiation and Exemptions

The final rule includes substantiation questions in 40 CFR 703.5(b) largely as set out in the proposed rule. As suggested in the proposed rule, the final rule omits a patent-specific question in favor of including the issue of patents in another question. The provisions concerning substantiation exemptions are as proposed.

a. *Patents.* The final rule omits a substantiation question exclusively concerned with patents, for the reasons discussed in the proposed rule and supported by public comment. Instead, where information claimed as confidential appears in some form in a patent or patent application, persons submitting those claims must address this public disclosure in their answer to the question on public disclosures more generally, 40 CFR 703.5(b)(3)(iii). Failure to address such a patent disclosure in the substantiation increases the risk that EPA will determine the information not entitled to confidential treatment. Further discussion of comments concerning CBI and patents is included in the Response to Comments for this rule (Ref. 8).

b. *Trade secrets.* Consistent with the proposed rule, the final rule omits a substantiation question specifically concerning trade secrets. See discussion in the preamble to the proposed rule (Ref. 6).

c. *Specificity of competitive harm.* EPA received several comments on the substantiation question concerning substantial competitive harm (40 CFR 703.5(b)(3)(i)), several supporting the proposed question, some advocating instead for a version of the question currently used for CDR submissions (40 CFR 711.30; “Will disclosure of the information claimed as confidential likely cause substantial harm to your business's competitive position? If you answered yes, describe the substantial

harmful effects that would likely result to your competitive position if the information is disclosed, including but not limited to how a competitor could use such information, and the causal relationship between the disclosure and the harmful effects”), or clarification, elaboration, or other changes from the proposed question. The final rule uses the proposed version of the question. Submitters may continue to use existing guidance describing EPA’s expectations for substantiation and may contact EPA regarding case-specific substantiation questions. Guidance and current staff contact information is available at <https://www.epa.gov/tsca-cbi>.

d. *Exemptions.* The final rule provisions at 40 CFR 703.5(b)(5) concerning substantiation exemptions in TSCA section 14(c)(2) are the same as proposed. EPA received limited comment concerning the exemption at TSCA section 14(c)(2)(G), for the specific identity of chemicals that have not yet been introduced into commerce, arguing that because the exemption may only be applied to claims made up until the substance is introduced into commerce, EPA has an obligation to revisit those pre-commerce claims once the substance has been introduced into commerce. While EPA agrees that new claims for the same information would no longer be exempt from the substantiation requirement once the chemical is introduced into commerce, there is nothing in the statute to suggest that EPA is required to revisit those prior claims. Indeed, CBI claims are generally only reviewed as required by TSCA section 14(g) (within 90 days of submission) or as permitted or required pursuant to one of the provisions of TSCA section 14(f). The filing of a Notice of Commencement (NOC), for example, does not trigger a mandatory review of prior CBI claims for the subject chemical substance by the same submitter.

3. Public Copies of Submissions

40 CFR 703.5(c) of the final rule includes a requirement that TSCA submitters include a public copy (sometimes referred to as a “sanitized copy”) of their submission, though 40 CFR 703.5(c)(1) limits this requirement to unfiled data, such as study reports and other documents that might be submitted as attachments to a reporting form. Most TSCA submissions that are made on a standard reporting form include individual data fields that each have a checkbox-type indicator for confidentiality claims. In the case of these forms, a public copy is either already generated automatically, or the reporting tool could be updated to

perform this function in future enhancements of CDX. Commenters generally supported this provision in the proposal, though some argued that EPA should further elaborate in the rule on how and when public copies would be made available, or that EPA should reject entire submissions or disregard CBI claims in submissions with incomplete or possibly incomplete public copies. The Response to Comments document (Ref. 8) elaborates on EPA’s current and planned practices for making public copies of TSCA submissions available, while noting that committing many of these practices to a rule is beyond the intended scope of this rulemaking activity except to the extent EPA finds the public copy to be deficient. The final rule provisions concerning treatment of deficiencies including missing or incomplete public copies are elaborated in Unit IV.D.6.

4. Supporting Statement and Certification

The final rule at 40 CFR 703.5(a) includes certification and supporting statements as set out in TSCA section 14, which are consolidated into one certification that is automatically incorporated into most TSCA reporting forms. TSCA submitters who for unusual and case-specific reasons are not able to provide their submission via CDX must assure that the consolidated statement is included in their submission. This provision is unchanged from the proposal.

5. Generic Names

The final rule includes provisions specifying requirements for generic chemical names, which are used in place of specific chemical names in public documents mentioning substances with confidential specific chemical identities. 40 CFR 703.5(d). The requirements cover when and how such generic names must be submitted, some basic requirements, and procedures for resolving disagreements about the adequacy of a given generic name. TSCA section 14(c)(1)(C) requires the submission of a generic name any time a specific chemical identity is claimed as confidential. This provision further requires that the generic name be “structurally descriptive” and that it “describe the chemical structure [. . .] as specifically as practicable” while also protecting the features of the chemical substance that are claimed confidential or where disclosure would likely cause substantial harm. 15 U.S.C. 2613(c)(1)(C)(ii). The generic name must also be consistent with the generic name guidance developed in accordance with

TSCA section 14(c)(4)(A), 15 U.S.C. 2613(c)(1)(C)(i) (Ref. 7).

The generic name provisions in the final rule are the same as were proposed. EPA received a few public comments on these provisions, questioning incorporation of elements of EPA’s generic name guidance into the rule, urging that EPA should undertake a CBI review of every generic name submitted under TSCA section 14, and suggesting that procedures permitting negotiation of generic names or permitting correction of deficiencies that EPA identifies with a generic name are too complex or are unnecessary, among other comments.

EPA concluded that incorporation of elements of the generic name guidance into the rule provides helpful clarification concerning minimum generic name requirements. Despite that clarification, however, EPA’s experience is that, in some instances, disagreement regarding the sufficiency of a generic name may be unavoidable. Therefore, the final rule sets forth a streamlined process for negotiating generic names in TSCA section 5 Notices of Commencement (40 CFR 720.102) and introduces a provision for EPA to provide an opportunity to correct deficient generic names in any TSCA submission (40 CFR 703.5(e)). The substantiation exemption for certain specific chemical identities contained in section 14(c)(2)(G) and corresponding exclusions from routine CBI review under TSCA section 14(g) indicate that substantive review of the sufficiency of every generic name at the time of submission is both in excess of TSCA requirements and impractical (especially where the substantiation necessary to complete such a review is neither required nor provided). The Response to Comments document provides more detailed discussion of these comments. (Ref. 8.)

6. Deficient Submissions

The clear requirements in the final rule regarding assertion of CBI claims, combined with recent improvements to TSCA reporting tools including near-universal electronic reporting, should significantly reduce the incidence of procedural deficiencies. Nonetheless, EPA does not expect that these will prevent all such problems. EPA is therefore retaining the proposed deficiency provisions in the final rule at 40 CFR 703.5(e).

Some public commenters advocated that the short correction period provided in the rule should be longer, and/or that EPA should give one or more additional notices, using both electronic and paper means of

communication. Others criticized providing any such opportunity to correct deficiencies, arguing that it would deprive the public of information that should be treated as non-confidential and that EPA should instead either reject such submissions outright, or immediately disclose the information subject to the deficient claim. As elaborated in the Response to Comments Document, the time period for correction of deficiencies is necessarily quite short, given statutory constraints on the time for CBI review and reviews under other parts of TSCA, such as TSCA section 5 (Ref. 8). As is also elaborated in the Response to Comments Document (Ref. 8) and in Unit IV.D.7. of this document, it is now a practical necessity that EPA and TSCA submitters rely primarily on electronic communications and notices made through CDX. *Id.*

By relying on electronic communications and keeping the period for correcting deficiencies short, EPA believes information not entitled to confidential treatment will be available to the public more quickly using the approach in the final rule (which also briefly pauses other statutory review periods, such as under TSCA section 5, such that the public is not deprived of the materials for any longer than it takes to identify the deficiency) than if EPA instead rejected the whole submission or proceeded to immediately release the information (actions, especially in the latter case, that could be expected to precipitate protracted litigation over an Agency action that could be seen as unduly punitive, arbitrary, and beyond statutory authority).

7. Electronic Reporting

The final rule requires, with very limited exceptions, that all TSCA submissions that include CBI claims must be submitted electronically. 40 CFR 703.5(f). This requirement most notably affects reporting under TSCA section 8(e), export notifications under TSCA section 12(b), and polymer exemption notices under TSCA section 5, for which electronic reporting is required for the first time in today's final rule. Voluntary e-reporting was already available for TSCA sections 8(e) and 12(b) notices, so those existing reporting tools will be updated in accordance with the final rule and will become mandatory to use for reporting. A new reporting tool will be available for submitting annual polymer exemption notices. A few commenters expressed concern over reliance on electronic reporting, citing past incidences of technical difficulties with providing electronic submissions via

CDX, especially related to 2020 CDR reporting (Ref. 8). EPA notes that in the case of 2020 CDR reporting, EPA moved quickly to correct the technical problems and extended the reporting deadline to accommodate reporters who had issues. Similar problems, many of which were related to both the large size of individual submissions and the peak volume of submissions being made around the same time, are fairly unique to the CDR rule reporting and would not be expected with TSCA section 8(e), TSCA section 12(b), or polymer exemption reporting, as the former two submission types are submitted throughout the year (not all at once) and for all three submission types, most submissions are fairly small. EPA expects that in the case technical reporting issues such as occasionally encountered in the 2020 CDR reporting period do recur in the future, the Agency would continue its practice of promptly addressing the problem and making appropriate accommodations (such as extending reporting deadlines). Also, noting one comment concerned with potential legal barriers to electronic reporting, such as when a submission might include classified information or otherwise include handling restrictions distinct from CBI claims, EPA expects to continue to handle these unusual and rare situations on a case-by-case basis, in accordance with their special legal and technical needs.

8. Requirement To Report Health and Safety Information Using OECD Harmonized Templates

EPA is finalizing the requirement to provide health and safety information using the appropriate OECD harmonized template (OHT), when such a template is available. 40 CFR 703.5(g). As explained in the preamble to the proposed rule, this requirement would be *in addition to* existing requirements to provide a full study report. EPA received some non-specific comments suggesting that the reporting burden associated with filling in such templates would be more substantial than EPA estimated, but these comments provided no alternative estimate. Use of the templates is already required for submitting data to regulatory authorities in other countries (*e.g.*, to the European Chemicals Agency (ECHA)) and international programs with strong U.S. participation and support encourage and facilitate reciprocal acceptance and use of data and non-duplication of chemical safety testing (see, *e.g.*, the OECD Mutual Acceptance of Data (MAD) system, <https://www.oecd.org/env/ehs/mutualacceptanceofdatamad>.

htm). Thus, in many if not most cases, companies or groups of companies conducting and/or submitting such chemical safety testing in the U.S will have already or would otherwise be required to fill out such templates anyway when providing the same information to regulatory authorities in other countries. Templated data will make CBI review of the submission more efficient (by aiding in identification of CBI claims) and aid in data sharing and dissemination within EPA and in public databases. EPA intends to elaborate on instructions for including OHT files (*e.g.*, currently acceptable file types and IUCLID software versions) as appropriate in individual reporting rules or orders, and/or in the applicable reporting tool instruction documents.

9. Maintenance of Company Contact Information and Communications Concerning Claims

The final rule provisions concerning maintenance of company contact information and reliance on electronic notices concerning CBI claims are as proposed. 40 CFR 703.5(h). EPA received several comments in favor of EPA providing redundant multi-media notices (electronic, paper mail, email, etc.) and concerned with the burden of maintaining contact information for each submission over time. As explained in the preamble to the proposed rule, it is EPA's experience that providing notice by other permissible means, such as via certified mail, does not necessarily better assure prompt delivery and access by its intended recipient than would EPA's proposed and preferred shift to reliance on electronic notices. For those commenters who advocated an email in addition to a CDX-delivered electronic notice, EPA notes that this is already occurring—each CDX notice coincides with a more generic email notice to the email address provided by the company contact.

Maintaining contact information for individual submissions is an inescapable consequence of the Lautenberg amendments, particularly since most CBI claims now expire after ten years unless reasserted by the submitter. The TSCA section 14(f) CBI review provisions also call for submission-specific company contact maintenance, in that those types of CBI review almost always require some notice to the company, both that the review is taking place and for the purpose of permitting submission of substantiation. Such reviews can take place at any time after a submission is made. EPA has created new reporting

tools that permit a company to request copies of record it may have lost access to by turnover in personnel or to provide updated contact information for one or more company submissions.

More broadly, EPA strongly suggests that companies develop internal practices to assure that a current company contact is maintained for each of their submissions including CBI. This might include, for example, use of email addresses that more than one person can access to receive CBI notices, a limited-access internal list of submission passphrases, or other procedures to better assure that passphrases and TSCA submission-specific information is known to or available to more than one person and isn't lost to the company when any one of its personnel are suddenly unavailable.

10. Withdrawing Claims

The final rule adopts the proposed provisions on withdrawing claims, which provide instructions for withdrawing claims originally made in an electronic submission, and for withdrawing claims originally made on paper or in an electronic submission no longer accessible to the company. 40 CFR 703.5(i).

11. Amending a Public Copy Following Claim Denial or Expiration

Public commentary was divided on who should be responsible for updating public copies of submissions to make newly non-CBI information available (the submitting company or EPA); other commenters suggested that making this information available need not be a priority unless a specific request for it was pending (e.g., a FOIA request). Based on its experience, EPA has concluded that companies submitting CBI claims should retain primary responsibility for updating public copies. Because the company best understands the intended scope and purpose of its original CBI claim(s), that company is in the best position to determine with precision which of its claims remain and assure these are indicated in the public copy accurately prior to release of the data. If EPA must occasionally dispute the scope of the remaining claims indicated by the submitter, EPA and the submitter could resolve this issue prior to release of the data, which is not possible when EPA prepares and releases the updated public copy without the involvement of the submitter. The final rule does include some minor amendments to clarify how EPA will append public copies to make newly non-CBI information available, in cases where

EPA must perform this function. 40 CFR 703.5(j).

E. EPA Review of Confidentiality Claims

1. Representative Subset

EPA received several comments on selection of the representative subset (40 CFR 703.7(a)), especially on the submissions it proposed to exclude from the subset as not being especially representative of TSCA submissions more generally. The final rule maintains the proposed case selection methodology (one in four TSCA submissions with non-exempt CBI claims for information other than chemical identity) but clarifies that this is the method EPA will use in general. EPA believes that some flexibility is appropriate here in case it might occasionally be necessary to issue additional confidentiality determinations to ensure that the Agency is meeting the minimum 25% required by TSCA section 14(g)(1)(C)(ii). The final rule also maintains the proposed exclusions from the representative subset, including certain pre-submission types of correspondence intended mainly to ascertain subsequent TSCA reporting obligations (e.g., *bona fide* notices under 40 CFR 720.25), occasional submissions that may be excluded from the otherwise nearly universal electronic reporting requirement, and amendments. In general, EPA believes that excluding these submissions is appropriate and will not significantly affect the total number of claims reviewed because these submissions may not contain many claims in the first place, the claims they do include are or will be duplicated in other submissions, and/or the submission type is relatively rare.

2. Substantive Criteria

TSCA itself does not specify the criteria that must be used in making a confidentiality determination, so EPA proposed and will retain in this final rule (40 CFR 703.7(f)) elements drawn from TSCA section 14(b) limitations of confidentiality protections, TSCA section 14(c) requirements to assert confidentiality claims, as well as EPA's long pre-existing criteria for evaluation of confidentiality claims as set out in 40 CFR 2.208.

Some commenters suggested a longer list of criteria or somewhat different wording to more strongly emphasize some parts of some criteria over others. EPA has declined most of these suggestions as EPA believes them to be unnecessary and unlikely to influence the outcome of a CBI determination. In response to one comment noting that a

FOIA-specific criterion was missing from the proposed 14(g) substantive criteria in 703.7 (it was proposed in 703.8 only for FOIA-prompted reviews under TSCA section 14(f)), EPA has made the substantive criteria uniform for any CBI determination. Though introducing some redundancy with the other criteria, EPA believes that one set of criteria for all reviews improves clarity and consistency between reviews.

EPA has declined the suggestion of one commenter that the criterion mentioning the limited confidentiality protections for health and safety study data (40 CFR 703.7(f)(5)) should be expanded to permit generic name to stand in for specific identity in any health and safety study for which the submitter wishes to assert a CBI claim. Instead, the study report would refer only to the generic name of the substance. The commenter supposed that simply not including the specific chemical identity in the study report could avoid the section 14(b) limitations on CBI protections in health and safety data. However, taking the commenter's suggestion would be contrary to longstanding EPA policy and rules stating that chemical identity is always considered part of a study (e.g., 40 CFR 720.3(k)); ignore the fact that health and safety studies are usually submitted as part of (attachments to) various TSCA reporting forms that also specifically identify the chemical; and not reflect the fact that chemical identity may be protected as CBI, need not be substantiated, and will not be routinely reviewed (under TSCA section 14(g)) until the chemical substance is introduced into U.S. commerce. However, the criterion has been clarified in the final rule to reflect that the limitations on confidentiality protections don't apply to all health and safety information that might be submitted under TSCA (e.g., data on R&D substances, prior to premanufacture notification).

3. Reconsideration Process

After considering comment on the proposal, EPA has decided to omit the reconsideration process (for denied CBI claims) from the final rule (Ref. 6). While some commenters supported the proposal, others did not, describing it as biased, open-ended, and lacking in transparency. EPA now believes that codifying a reconsideration process is unnecessary. If a person believes that a determination was incorrect or has questions about the determination, they may contact EPA (using the contact information in the final CBI determination letter) about their

concerns prior to filing a judicial appeal.

F. Related or Corresponding Revisions to Other TSCA Rules

1. Revisions to 40 CFR Parts 702, 704, 707, 716, 717, 723, and 790

The final rule replaces the CBI provisions of several TSCA rules with a cross reference to 40 CFR part 703 to centralize the CBI rules and make them more consistent among submission types. EPA received some comment advocating for retaining some of the existing CBI provisions, but EPA believes this is unnecessary, redundant, and/or needlessly inconsistent with the final CBI rules centralized in 40 CFR part 703. For further discussion, see the Response to Comments (Ref. 8).

2. Clarification of TSCA Section 12(b) Rules

The language in 40 CFR part 707 is revised in the final rule to cross reference 40 CFR part 703 for CBI reporting requirements, to require electronic reporting, and to clarify that it is generally not necessary to list confidential specific chemical identities in a TSCA section 12(b) report. EPA received some public comment criticizing this provision, misunderstanding the clarification as rescinding a previous requirement to provide specific chemical identities in TSCA section 12(b) notices. Part 707 regulations never included such a requirement, though some submitters unnecessarily provided such information anyway. The Response to Comments Document provides further clarification of the pre-existing rule and elaborates on how EPA processes TSCA section 12(b) notices without need for a confidential specific chemical identity in the report (Ref. 8).

3. Revision in 40 CFR 717.17 and 723.250 To Reflect Electronic Reporting

The final rule revises 40 CFR parts 717 and 723 to reflect that TSCA section 8(c) incident reports and TSCA section 5 polymer exemption notices must be submitted electronically.

4. Revisions to Confidentiality Provisions in the Premanufacture Notice (PMN) and Microbial Commercial Activity Notice (MCAN) Rules

The final rule revises 40 CFR parts 720 and 725 as proposed. Some public commenters also favored retaining more of the CBI provisions in 40 CFR part 720. A commenter asserted that the proposed revisions to 40 CFR 720.85 omitted necessary existing statements that are not sufficiently duplicated in the final rule—EPA disagrees and notes

that the commenter in some areas misunderstands 40 CFR 720.85. The language in 40 CFR part 720.85(a) is mostly redundant with TSCA section 14, other provisions of the final rule, or both. Under the final rule, persons may assert CBI claims for chemical identity in a PMN, but they must also submit a generic name consistent with TSCA section 14(c). Persons who would like to consult EPA concerning an appropriate generic name may continue to do so through the pre-notice consultation process. See: <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tasca/filing-pre-manufacture-notice-epa#pre-notice>.

Much of 40 CFR 720.85(b) is retained in the final rule, but has been moved to 40 CFR 720.102, while the substantiation provisions are replaced with the substantiation provisions in 40 CFR part 703. The provision in section 720.85(b)(1), providing that a CBI claim for chemical identity may not be asserted in an NOC unless that CBI claim has been asserted for the underlying PMN, is not necessary. If the chemical identity is not claimed as CBI in the PMN, the chemical identity is published in the public notice required by TSCA section 5(d)(2). PMNs and NOCs are identified by the same case number, providing a public link between the NOC and the PMN. Upon required TSCA section 14(g) review of the chemical identity claim in the NOC, EPA would not uphold a confidentiality claim that was not made in the PMN. Further discussion is available in the Response to Comments document (Ref. 8).

One commenter advocated retaining most of 40 CFR 720.90 (except (a)(3), (b)(2)(iii), and (c)(3)), arguing that chemical identity claims should not be permitted in health and safety studies at the PMN stage, but that if EPA continues to permit such claims in the PMN, the PMN claim should be re-reviewed when an NOC is filed and chemical identity should be disclosed. EPA disagrees. Chemical identity claims are permitted in the PMN submission including attachments, and such claims are exempt from upfront substantiation requirements under TSCA section 14(c)(2)(G) and from routine review under TSCA section 14(g). TSCA section 14(g) requires that EPA review certain CBI claims within 90 days of submission. In nearly all circumstances, an NOC is filed well more than 90 days after the PMN, usually months or sometimes years later (or not at all). The NOC is also, while linked to the PMN submission, a different TSCA submission—one that does not include health and safety studies. NOCs are

subject to review under TSCA section 14(g), as are PMNs, but the filing of an NOC does not open or reopen the TSCA section 14(g) review of the PMN filed previously. Instead, the PMN may be reviewed or re-reviewed pursuant to TSCA section 14(f), under one of the mandatory or discretionary provisions, where applicable. Even following TSCA section 14(f) review, many chemical identity claims in health and safety studies will still be valid, as TSCA section 14(b) includes exceptions from information that is not protected from disclosure, including information that discloses processes used in the manufacture of a substance or portion of mixture information.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these documents and other information considered by EPA, including documents that are referenced within the documents that are included in the docket, even if the referenced document is not physically located in the docket. For assistance in locating these other documents, please consult the person listed under **FOR FURTHER INFORMATION CONTACT**.

1. U.S. EPA. Electronic Reporting under the Toxic Substances Control Act; Final Rule. **Federal Register**. 78 FR 72818, December 4, 2013 (FRL-9394-6).
2. U.S. EPA. Economic Impact Analysis for the Procedures for Submitting Information Subject to Business Confidentiality Claims under the Toxic Substances Control Act (TSCA); Final Rule (RIN 2070-AK68). April 2023.
3. U.S. EPA. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Final Rule. **Federal Register**. 85 FR 13062, March 6, 2020 (FRL-10005-48).
4. U.S. EPA. TSCA Chemical Substances; Unique Identifier Assignment and Application Policy; Notice of Availability. **Federal Register**. 83 FR 30168, June 27, 2018 (FRL-9979-59).
5. U.S. EPA. Guidance on Expanded Access to TSCA Confidential Business Information; Notice of Availability. **Federal Register**. 83 FR 30171, June 27, 2018 (FRL-9979-75).
6. U.S. EPA. Confidential Business Information Claims under the Toxic Substances Control Act (TSCA); Proposed Rule. **Federal Register**. 87 FR 29078, May 12, 2022 (FRL-8223-01-OCSPF).
7. U.S. EPA. Guidance for Creating Generic Names for Confidential Chemical Identity Reporting under TSCA. Publication ID No. EPA 743B18001. June 2018. Available at: https://www.epa.gov/sites/production/files/2018-06/documents/san6814_guidance_for_creating_tasca_generic_names_2018-06-13_final.pdf.

8. U.S. EPA. Confidential Business Information Claims under the Toxic Substances Control Act (TSCA); Final Rule (RIN 2070-AK68). Response to Comments Document. April 2023.
9. U.S. EPA. Information Collection Request (ICR) entitled: Confidential Business Information Claims under the Toxic Substances Control Act (TSCA)—Final Rule (RIN 2070-AK68). EPA ICR No.: 2706.02; OMB Control No.: 2070-0223. February 2023.
10. U.S. EPA. Response to Comments on the Proposed Rule, Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory. February 4, 2020, available at <https://www.regulations.gov/document/EPA-HQ-OPPT-2018-0320-0061>.
11. U.S. EPA. TSCA section 8(a)(7) Reporting and Recordkeeping Requirements for the Perfluoroalkyl and Polyfluoroalkyl (PFAS) Substances; Notice of Data Availability and Request for Comment. **Federal Register**. 87 FR 72439, Nov. 25, 2022 (FRL-7902-4)

VI. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at <https://www.epa.gov/laws-regulations/laws-and-executive-orders#influence>.

A. Executive Orders 12866: Regulatory Planning and Review and 14094: Modernizing Regulatory Review

This action is not a significant regulatory action as defined in Executive Order 12866 (58 FR 51735, October 4, 1993), as amended by Executive Order 14094 (88 FR 21879, April 11, 2023), and was therefore not subject to Executive Order 12866 review.

B. Paperwork Reduction Act (PRA)

The information collection activities in this final rule have been submitted to OMB for approval under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR) document that EPA prepared is assigned EPA ICR No. 2706.02 and OMB Control No. 2070-0223 (Ref. 9). You can find a copy of the ICR in the docket for this action, and it is briefly summarized here. The information collection requirements are not enforceable until OMB approves them.

The reporting requirements identified in this final rule implement statutory requirements in TSCA section 14, including the new requirements that persons submitting information under TSCA must substantiate most confidentiality claims at the time of submission, as well as additional certification and generic name requirements. In order to maintain most claims beyond a 10-year period,

submitters will also be required to reassert and substantiate those claims. Several new requirements also apply to EPA, including requirements to review and approve or deny all chemical identity claims asserted concerning substances that are offered for commercial distribution, as well a subset of all other confidentiality claims, within 90 days of the claim being asserted. Further requirements that EPA review all confidentiality claims concerning substances listed as active on the TSCA Inventory, a requirement to assign and apply Unique Identifiers to substances with approved confidentiality claims for chemical identity, as well as new provisions providing expanded access to TSCA CBI, have been discussed in previous **Federal Register** Documents. Additionally, TSCA rules promulgated since the Lautenberg amendments have included confidentiality provisions conforming to the amendments (*e.g.*, 40 CFR parts 710 and 711).

Respondents/affected entities: Firms asserting claims for confidentiality in submissions to EPA under TSCA. See also Unit I.A.

Respondent's obligation to respond: Mandatory (TSCA section 14; 15 U.S.C. 2613).

Frequency of response: On occasion.
Total estimated number of respondents: 1,100 firms with an estimated additional 55 new firms each year.

Total estimated number of responses: 1,100.

Total estimated burden: 2,945 hours in the first year and 523 hours every subsequent year. Burden is defined at 5 CFR 1320.3(b).

Total estimated cost: \$ 272,804 in the first year and \$ 45,592 every subsequent year, which includes \$ 0 annualized capital or operation and maintenance costs.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number. The OMB control numbers for the EPA regulations in 40 CFR are listed in 40 CFR part 9. When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

I certify that this action will not have a significant economic impact on a substantial number of small entities under the RFA, 5 U.S.C. 601 *et seq.* The

small entities subject to the requirements of this action are chemical manufacturers (including importers). EPA estimates that 1,001 small firms would be affected by the proposed requirements. Of those small firms, 100% would have cost impacts of less than 1 percent of annual revenues, which EPA has determined does not qualify as a significant impact. Details of this analysis are presented in the Economic Analysis (Ref. 2), which is available in the docket. We have therefore concluded that this action will not have a significant adverse economic impact on all directly regulated small entities.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531-1538, and does not significantly or uniquely affect small governments. The action imposes no enforceable duty on any State, local or Tribal governments or the private sector.

E. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 4, 1999) because it will not have substantial direct effects on the states, on the relationship between the national government and the states, or on the distribution of power and responsibilities among the various levels of government.

F. Executive Order 13175: Consultation and Coordination With Indian Tribal Governments

This action does not have Tribal implications as specified in Executive Order 13175 (65 FR 67249, November 9, 2000) because it will not have substantial direct effects on Tribal governments, on the relationship between the Federal government and the Indian Tribes, or on the distribution of power and responsibilities between the Federal government and Indian Tribes. It does not have substantial direct effects on Tribal government because EPA does not anticipate that Tribal governments will often make TSCA submissions, let alone those for which they would assert a CBI claim necessitating substantiation and other requirements under TSCA and this rule, so this rulemaking is not expected to impose substantial direct compliance costs on Tribal governments. Thus, Executive Order 13175 does not apply to this action.

G. Executive Order 13045: Protection of Children From Environmental Health Risks and Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997) as applying only to those regulatory actions that concern environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of “covered regulatory action” in section 2–202 of Executive Order 13045. This action is not subject to Executive Order 13045 because it does not concern environmental health risk or safety risk.

Although this action does not concern human health or safety risk, it does set clear procedures for confidentiality claims made by reporting entities under TSCA, this action is expected to improve the quality of such claims, reduce unnecessary and unsupported claims, and is anticipated to result in more information being available to the public. This action does not address any human health or environmental risks and does not affect the level of protection provided to human health or the environment. Information submitted under TSCA can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment and as noted in this paragraph, may make more of this information available to the public.

H. Executive Order 13211: Actions That Significantly Affect Energy Supply, Distribution, or Use

This action is not a subject to Executive Order 13211 (66 FR 28355, May 22, 2001) because it is not a significant regulatory action under Executive Order 12866 and has not otherwise been designated as a significant energy action by the Administrator of the Office of Information and Regulatory Affairs.

I. National Technology Transfer and Advancement Act (NTTAA)

This action does not involve technical standards that would require Agency consideration under NTTAA section 12(d), 15 U.S.C. 272.

J. Executive Order 12898: Federal Actions To Address Environmental Justice in Minority Populations and Low-Income Populations

Executive Order 12898 (59 FR 7629, February 16, 1994) directs Federal agencies, to the greatest extent practicable and permitted by law, to make environmental justice part of their

mission by identifying and addressing, as appropriate, disproportionately high and adverse human health or environmental effects of their programs, policies, and activities on minority populations (people of color and/or indigenous peoples) and low-income populations.

EPA believes that this action does not directly concern human health or environmental conditions and therefore cannot reasonably be evaluated with respect to potentially disproportionate and adverse effects on people of color, low-income populations and/or indigenous peoples. This action does not directly address any human health or environmental risks and does not directly affect the level of protection provided to human health or the environment. However, although this action does not directly concern human health or environmental conditions, in setting clear procedures for confidentiality claims made by reporting entities under TSCA, this action is expected to improve the quality of such claims, reduce unnecessary and unsupported claims, and is anticipated to result in more information being available to the public. By ensuring uniform substantiation of CBI claims, electronic reporting requirements, certification statements, clarifying how EPA treats certain information initially obtained in a context other than TSCA, and the process for maintenance or withdrawal of confidentiality claims, EPA is improving communications and transparency to the public and promoting consistency for the regulated community. Improved communication and transparency has inherent informational benefits including increasing understanding and awareness of potential issues related to chemical information. Information submitted under TSCA can also be used by government agencies and others to identify potential problems, set priorities, and take appropriate steps to reduce any potential risks to human health and the environment and as noted in this paragraph, may make more of this information available to the public. Therefore, the informational benefits of the action are likely to have a positive impact on the human health and environmental impacts of all populations, including minority populations, low-income populations, and indigenous peoples.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.*, and EPA will submit a rule report to each House of the Congress and to the Comptroller General

of the United States. This action is not a “major rule” as defined by 5 U.S.C. 804(2).

List of Subjects

40 CFR Part 2

Administrative practice and procedure, Confidential business information, Courts, Environmental protection, Freedom of information, Government employees.

40 CFR Part 702

Administrative practice and procedure, Chemicals, Environmental protection, Hazardous substances.

40 CFR Part 703

Administrative practice and procedure, Chemicals, Confidential business information, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 704

Chemicals, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 707

Chemicals, Environmental protection, Exports, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 716

Chemicals, Confidential business information, Environmental protection, Hazardous substances, Health, Reporting and recordkeeping requirements, Safety.

40 CFR Part 717

Chemicals, Environmental protection, Hazardous substances, Reporting and recordkeeping requirements.

40 CFR Part 720

Chemicals, Environmental protection, Hazardous substances, Imports, Reporting and recordkeeping requirements.

40 CFR Part 723

Chemicals, Environmental protection, Hazardous substances, Phosphate, Reporting and recordkeeping requirements.

40 CFR Part 725

Administrative practice and procedure, Biologics, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

40 CFR Part 790

Administrative practice and procedure, Biologics, Chemicals, Environmental protection, Hazardous substances, Imports, Labeling, Microorganisms, Occupational safety and health, Reporting and recordkeeping requirements.

Authority: 15 U.S.C. 2603, 2604, 2605, 2607, 2613, 2619, and 2625 *et seq.*

Michael S. Regan,
Administrator.

Therefore, for the reasons stated in the preamble, 40 CFR chapter I is amended as follows:

PART 2—PUBLIC INFORMATION

■ 1. The authority citation for part 2 continues to read as follows:

Authority: 15 U.S.C 2613.

■ 2. Revise § 2.306 to read as follows:

§ 2.306 Special rules governing certain information obtained under the Toxic Substances Control Act.

(a) *Definitions.* For the purposes of this section:

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

Chemical substance has the meaning given it in section 3(2) of the Act, 15 U.S.C. 2602(2).

EPA Legal Office means the EPA Office of General Counsel and any EPA office over which the EPA General Counsel exercises supervisory authority.

Proceeding means any rulemaking, adjudication, or licensing conducted by EPA under the Act or under regulations which implement the Act, except for determinations under this subpart.

(b) *Applicability.* This section applies as set forth in 40 CFR 703.1.

(c) *Basic rules that apply without change.* Sections 2.210, 2.211, 2.212, 2.214, and 2.215 of this part apply without change to information to which this section applies. Unless otherwise specified in this section, the provisions in §§ 2.201 through 2.205 and 2.208 do not apply to information subject to this section. Instead, the provisions of 40 CFR part 703 provide the requirements and procedures relevant to confidentiality determinations for information submitted to EPA under the Act.

(d) *Disclosure in special circumstances.* (1) EPA intends to make disclosures pursuant to a request under section 14(d)(4), (5), or (6) of the Act for information to which this section applies in accordance with the requirements of the Act and any applicable EPA guidance required by section 14(c)(4)(B) of the Act.

(2) Section 2.209 applies to information to which this section applies, except that:

(i) The notification specified in § 2.209(b)(2) is 15 business days.

(ii) The following two additional provisions apply to § 2.209(c):

(A) The official purpose for which the information is needed must be in connection with the agency's duties under any law for protection of health or the environment or for specific law enforcement purposes; and

(B) EPA notifies the other agency that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the officers and employees of the other agency to the penalties in section 14(h) of the Act (15 U.S.C. 2613(h)).

(e) *Disclosure of information relevant in a proceeding.* (1) Under section 14(d)(7) of the Act (15 U.S.C. 2613(d)(7)), any information to which this section applies may be disclosed by EPA when the information is relevant in a proceeding under the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. However, any such disclosure shall be made in a manner that preserves the confidentiality of the information to the extent practicable without impairing the proceeding. Disclosure of information to which this section applies because of its relevance in a proceeding shall be made only in accordance with this paragraph (e).

(2) The provisions of § 2.301(g)(2) through (4) apply to disclosures under this paragraph (e).

(f) *Disclosure of information to contractors and subcontractors.* (1) Under section 14(d)(2) of the Act (15 U.S.C. 2613(d)(2)), any information to which this section applies shall be disclosed by EPA to a contractor or subcontractor of the United States if, in the opinion of the Administrator, the disclosure is necessary for the satisfactory performance of their work in connection with the Act, notwithstanding the fact that the information otherwise might be entitled to confidential treatment under this subpart. Subject to the limitations in this paragraph (f), information to which this section applies may be disclosed:

(i) To a contractor or subcontractor with EPA, if the EPA program office managing the contract first determines in writing that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract; or

(ii) To a contractor or subcontractor with an agency other than EPA, if the EPA program office which provides the information to that agency, contractor, or subcontractor first determines in writing, in consultation with the General Counsel, that such disclosure is necessary for the satisfactory performance by the contractor or subcontractor of the contract or subcontract.

(2) The provisions of § 2.301(h)(2)(i) through (iv) apply to disclosures under paragraph this (f).

(3) At the time any information is furnished to a contractor or subcontractor under this paragraph (f), the EPA office furnishing the information to the contractor or subcontractor shall notify the contractor or subcontractor that the information was acquired under authority of the Act and that any knowing disclosure of the information may subject the contractor or subcontractor and its employees to the penalties in section 14(h) of the Act (15 U.S.C. 2613(h)).

(g) *Disclosure of information when necessary to protect health or the environment against an unreasonable risk of injury.* (1) Under section 14(d)(3) of the Act (15 U.S.C. 2613(d)(3)), any information to which this section applies shall be disclosed by EPA if the Administrator determines that disclosure is necessary to protect health or the environment against an unreasonable risk of injury to health or the environment, without consideration of costs, or other non-risk factors, including an unreasonable risk to a potentially exposed or susceptible subpopulation identified as relevant by the Administrator under the conditions of use. However, any disclosure shall be made in a manner that preserves the confidentiality of the information to the extent not inconsistent with protecting health or the environment against the unreasonable risk of injury. Disclosure of information to which this section applies because of the need to protect health or the environment against an unreasonable risk of injury shall be made only in accordance with this paragraph (g).

(2) If any EPA office determines that there is an unreasonable risk of injury to health or the environment and that to protect health or the environment against the unreasonable risk of injury it is necessary to disclose information to which this section applies that otherwise might be entitled to confidential treatment under this subpart, the EPA office shall notify the EPA Legal Office in writing of the nature of the unreasonable risk of injury, the extent of the disclosure

proposed, how the proposed disclosure will serve to protect health or the environment against the unreasonable risk of injury, and the proposed date of disclosure. Such notification shall be made as soon as practicable after discovery of the unreasonable risk of injury. If the EPA office determines that the risk of injury is so imminent that it is impracticable to furnish written notification to the EPA Legal Office, the EPA office shall notify the EPA Legal Office orally.

(3) Upon receipt of notification under paragraph (g)(2) of this section, the EPA Legal Office shall make a determination in writing whether disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury. The EPA Legal Office shall also determine the extent of disclosure necessary to protect against the unreasonable risk of injury as well as when the disclosure must be made to protect against the unreasonable risk of injury.

(4) If the EPA Legal Office determines that disclosure of information to which this section applies that otherwise might be entitled to confidential treatment is necessary to protect health or the environment against an unreasonable risk of injury, the EPA Legal Office shall furnish notice to each affected business of the contemplated disclosure and of the Legal Office's determination. Such notice shall be made in writing, via either electronic notice as described in 40 CFR 703.5(h) or by certified mail, return receipt requested, at least 15 business days before the disclosure is to be made. The notice shall state the date upon which disclosure will be made. However, if the EPA Legal Office determines that disclosure of the information is necessary to protect against an imminent and substantial harm to health or the environment, no prior notification is necessary.

PART 702—GENERAL PRACTICES AND PROCEDURES

■ 3. The authority citation for part 702 continues to read as follows:

Authority: 15 U.S.C. 2605 and 2619.

■ 4. Amend § 702.37 by revising paragraph (d) to read as follows:

§ 702.37 Submission of manufacturer requests for risk evaluations.

* * * * *

(d) *Confidential business information.* Claims of confidentiality must be made

in accordance with the procedures described in 40 CFR part 703.

* * * * *

■ 5. Add part 703 to read as follows:

PART 703—CONFIDENTIALITY CLAIMS

Sec.

703.1 Purpose and applicability.

703.3 Definitions.

703.5 Requirements for asserting and maintaining confidentiality claims.

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

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

Authority: 15 U.S.C. 2613.

§ 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.

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.

PART 704—REPORTING AND RECORDKEEPING REQUIREMENTS

■ 6. The authority citation for part 704 continues to read as follows:

Authority: 15 U.S.C. 2607(a).

■ 7. Revise § 704.7 to read as follows:

§ 704.7 Confidential business information claims.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 707—CHEMICAL IMPORTS AND EXPORTS

■ 8. The authority citation for part 707 continues to read as follows:

Authority: 15 U.S.C. 2611(b) and 2612.

■ 9. Amend § 707.63 by:

■ a. Removing the paragraph designations (a) through (d) and listing the existing definitions in alphabetical order; and

■ b. Adding in alphabetical order a definition for “CDX”.

The addition reads as follows:

§ 707.63 Definitions.

* * * * *

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

* * * * *

■ 10. Revise § 707.65 to read as follows:

§ 707.65 Submission to the agency.

(a) For each action under TSCA triggering export notification, exporters must notify EPA of their export or intended export of each subject

chemical substance or mixture for which export notice is required under § 707.60 in accordance with the following:

(1)(i) The export notice must be for the first export or intended export by an exporter to a particular country in a calendar year when the chemical substance or mixture is the subject of an order issued, an action that is pending, or relief that has been granted under TSCA section 5(f), a rule that has been proposed or promulgated under TSCA section 6, or an action that is pending or relief that has been granted under TSCA section 7.

(ii) The export notice must only be for the first export or intended export by an exporter to a particular country when the chemical substance or mixture is the subject of an order issued, an action that is pending, or relief that has been granted under TSCA section 5(e), a rule that has been proposed or promulgated under TSCA section 5(a)(2), or when the submission of data is required under TSCA section 4 or 5(b). Under this paragraph, notice of export to a particular country is not required if an exporter previously submitted to EPA a notice of export to that country prior to January 16, 2007.

(2) The export notice must be submitted to EPA within seven days of forming the intent to export or on the date of export, whichever is earlier. A notice of intent to export must be based on a definite contractual obligation, or an equivalent intra-company agreement, to export the regulated chemical.

(b) If the EPA action that prompts the notice is a proposed rule, the requirement to submit export notices to EPA shall begin thirty days after publication of the action in the **Federal Register**.

(c) Export notices must be submitted via CDX, using the TSCA section 12(b) Export Notification Application or its successor.

- 11. Amend § 707.67 by revising paragraph (a) to read as follows:

§ 707.67 Contents of notice.

* * * * *

(a) The name of the regulated chemical as it appears in the TSCA section 4, 5, 6, and/or 7 action. For substances on the confidential portion of the TSCA Inventory, the substance must be identified by generic name and accession number, or by any other non-confidential identifier under which it is listed on the TSCA section 12(b) reporting list maintained by EPA and available in the TSCA section 12(b) Export Notification Application described in § 707.65(c). If a category is regulated, the name of the individual

regulated chemical within that category, as well as the category, must be given. The name must be that which appears in the TSCA Inventory if the chemical appears there.

* * * * *

- 12. Amend § 707.75 by revising paragraph (d) to read as follows:

§ 707.75 Confidentiality.

* * * * *

(d) Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 716—HEALTH AND SAFETY DATA REPORTING

- 12. The authority citation for part 716 continues to read as follows:

Authority: 15 U.S.C. 2607(d).

- 13. Revise § 716.55 to read as follows:

§ 716.55 Confidentiality claims.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 717—RECORDS AND REPORTS OF ALLEGATIONS THAT CHEMICAL SUBSTANCES CAUSE SIGNIFICANT ADVERSE REACTIONS TO HEALTH OR THE ENVIRONMENT

- 14. The authority citation for part 717 continues to read as follows:

Authority: 15 U.S.C. 2607(c).

- 15. Amend § 717.17 by revising paragraph (c) to read as follows:

§ 717.17 Inspection and reporting requirements.

* * * * *

(c) *How to Report.* When required to report, firms must submit copies of records via CDX <https://cdx.epa.gov/> using the EPA provided electronic reporting application.

- 16. Revise § 717.19 to read as follows:

§ 717.19 Confidentiality.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 720—PREMANUFACTURE NOTIFICATION

- 17. The authority citation for part 720 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, and 2613.

- 18. Revise § 720.80 to read as follows:

§ 720.80 General provisions.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

§ 720.85 [Removed]

- 19. Remove § 720.85.

§ 720.90 [Removed]

- 20. Remove § 720.90.

- 21. Revise § 720.95 to read as follows:

§ 720.95 Public file.

All information submitted with a notice, including any health and safety study and other supporting documentation, will become part of the public file for that notice, unless such materials are claimed confidential in accordance with procedures in 40 CFR 703.5. In addition, EPA may add materials to the public file, subject to subpart E of this part. Publicly available materials are available at the docket addresses in § 700.17(b)(1) and (2) of this subchapter and on EPA's website.

- 22. Amend § 720.102 by revising paragraph (c)(2) and adding paragraphs (e) and (f) to read as follows:

§ 720.102 Notice of commencement of manufacture or import.

* * * * *

(c) * * *

(2) If the submitter claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in 40 CFR part 703 and must be submitted via EPA Form 7710-56. If the submitter wants the chemical identity to be listed on the confidential portion of the TSCA Inventory, the chemical identity must be claimed as confidential and the submitter must also follow the certification, substantiation, and generic name requirements described 40 CFR part 703 and paragraphs (e) and (f) of this section. Otherwise, EPA will list the specific chemical identity on the public TSCA Inventory. Submitters who did not claim the chemical identity, submitter identity, or other information to be confidential in the PMN cannot claim this information as confidential in the notice of commencement.

* * * * *

(e) *Confidentiality.* (1) Any person who asserts a confidentiality claim for chemical identity in a Notice of Commencement submitted under this section must:

(i) Comply with generic name requirements described in 40 CFR part 703 and as specified in paragraph (f) of this section.

(ii) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the chemical substance the fact that the particular chemical substance is included on the confidential TSCA Inventory for

purposes of notification under section 5(a)(1)(A) of the Act.

(iii) Have available for the particular chemical substance, and agree to furnish to EPA upon request:

(A) An elemental analysis.

(B) Either an X-ray diffraction pattern (for inorganic substances), a mass spectrum (for most other substances), or an infrared spectrum of the particular chemical substance, or if such data do not resolve uncertainties with respect to the identity of the chemical substance, additional or alternative spectra or other data to identify the chemical substance.

(2) Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

(f) *Generic name.* If a submitter asserts a claim of confidentiality for chemical identity in a notice of commencement, they must provide a structurally descriptive generic name.

(1) Generic names must:

(i) Be structurally descriptive (*e.g.*, not a trade name);

(ii) Describe the chemical structure of the chemical substance as specifically as practicable while protecting only those features of the chemical structure that are claimed as confidential and disclosure of which would likely cause substantial harm to the competitive position of the person—the generic name should generally only obscure one structural feature, but in any case, should conceal only the feature(s) necessary to avoid a likelihood of substantial competitive harm to the submitter; and

(iii) Be consistent with guidance on the determination of structurally descriptive generic names, developed in accordance with TSCA section 14(c)(4)(A) (*e.g.*, *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*; available at <https://www.epa.gov/tscainventory/guidance-creating-generic-names-confidential-chemical-substance-identity-reporting>).

(2) Generic names will be reviewed by EPA at the time of submission.

(i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1) of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.

(ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in 40 CFR 703.5(f). EPA will provide 10 business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is

acceptable to the submitter (or if the submitter does not respond within the 10-day period), EPA will place that alternative generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the submitter's revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the substance will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the chemical identity claim and will likely deny the claim.

PART 723—PREMANUFACTURE NOTICE EXEMPTIONS

■ 23. The authority citation for part 723 continues to read as follows:

Authority: 15 U.S.C. 2604.

■ 24. Amend § 723.50 by revising paragraph (l) to read as follows:

§ 723.50 Chemical substances manufactured in quantities of 10,000 kilograms or less per year, and chemical substances with low environmental releases and human exposures.

* * * * *

(l) *Confidentiality.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

* * * * *

■ 25. Amend § 723.250 by revising paragraphs (f) introductory text and (n) to read as follows:

§ 723.250 Polymers.

* * * * *

(f) *Exemption report for polymers manufactured under the terms of this section.* For substances exempt under paragraphs (e)(1) through (3) of this section a report of manufacture or import must be submitted by January 31 of the year subsequent to initial manufacture. The report and accompanying claims must be submitted via CDX (<https://cdx.epa.gov/>), using the TSCA Section 5 Notices and Supports—ePMN application. See § 720.40(a)(2)(ii) of this subchapter for information on how to access e-PMN software. The notice must include:

* * * * *

(n) *Confidentiality.* Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

PART 725—REPORTING REQUIREMENTS AND REVIEW PROCESSES FOR MICROORGANISMS

■ 26. The authority citation for part 725 continues to read as follows:

Authority: 15 U.S.C. 2604, 2607, 2613, and 2625.

■ 27. Revise § 725.80 to read as follows:

§ 725.80 General provisions for confidentiality claims.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703, except as modified in this paragraph. In general, references to “chemical” or “chemical identity” in part 703 are equivalent to “microorganism” or “microorganism identity” for the purposes of this part.

(a) In place of § 703.5(b)(3)(v) of this subchapter, the following question must be answered: Has EPA, another Federal agency, or court made any confidentiality determination regarding information associated with this microorganism? If yes, please provide the circumstances associated with the prior determination, whether the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(b) In place of § 703.5(b)(4) of this subchapter, the following questions apply:

(1) Has the identity of the microorganism been kept confidential to the extent that competitors do not know it is being manufactured or imported into US commerce? If not, explain why the microorganism identity should still be afforded confidential status (*e.g.*, the microorganism 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 microorganism in the United States is publicly available).

(2) Does the microorganism leave the site of production or testing in a form which is accessible to the public or to competitors? If yes, please explain what measures have been taken to guard against the discovery of its identity. Further, what is the cost to a competitor, in time and money, to develop appropriate use conditions? What factors facilitate or impede product analysis?

§ 725.85 [Removed]

■ 28. Remove § 725.85.

§ 725.92 [Removed]

- 29. Remove § 725.92.

§ 725.94 [Removed]

- 30. Remove § 725.94.
- 31. Revise § 725.95 to read as follows:

§ 725.95 Public file.

All information submitted, including any health and safety study of a microorganism and other supporting documentation, will become part of the public file for that submission, unless such materials are claimed as confidential in accordance with this section. In addition, EPA may add materials to the public file, subject to subpart C of this part. Publicly available materials are available at the docket addresses in § 700.17(b)(1) and (2) of this subchapter and on EPA's website.

- 32. Amend § 725.190 by revising paragraph (c) and adding paragraphs (e) and (f) to read as follows:

§ 725.190 Notice of commencement of manufacture or import.

* * * * *

(c) *Information to be reported.* The NOC must contain the following information: Specific microorganism identity, MCAN number, and the date when manufacture or import commences. If the person claims any information on the form as confidential, the claim must be asserted and substantiated in accordance with the requirements described in part 703 of this subchapter and § 725.80, as indicated in EPA Form 7710–56. If the submitter wants the microorganism identity to be listed on the confidential portion of the TSCA Inventory, the microorganism identity must be claimed as confidential and also follow the certification, substantiation, and generic name requirements described in part 703 of this subchapter and paragraphs (e) and (f) of this section.

* * * * *

(e) *Requirements for assertion.* Any person who asserts a confidentiality claim for microorganism identity must:

(1) Comply with the requirements of paragraph (f) of this section regarding submission of a generic name.

(2) Agree that EPA may disclose to a person with a *bona fide* intent to manufacture or import the microorganism the fact that the particular microorganism is included on the confidential TSCA Inventory for purposes of notification under section 5(a)(1)(A) of the Act.

(3) Have available and agree to furnish to EPA upon request the taxonomic designations and supplemental information required by § 725.12.

(4) Make claims of confidentiality in accordance with the procedures described in 40 CFR part 703.

(f) *Generic name.* If a submitter asserts a claim of confidentiality for microorganism identity in a notice of commencement, they must provide a generic name.

(1) Generic names must:

(i) Be structurally descriptive (*e.g.*, not a trade name); and

(ii) Be consistent with guidance on the determination of structurally descriptive generic names, developed in accordance with section 14(c)(4)(A) of the Act (*e.g.*, *Guidance for Creating Generic Names for Confidential Chemical Substance Identity Reporting under TSCA*). Generic names for microorganisms may only mask the portion of microorganism identity that the submitter believes is proprietary (considering that the identity of a microorganism to be listed on the TSCA Inventory must include taxonomic designations (genus, species, and strain), key phenotypic traits, key genotypic traits and modifications, genetic material that has been introduced or modified, any vector constructs used, cellular location of introduced or modified genes, number and type of genes introduced or modified, and method of construction or modification). Taxonomic designation (in most cases down to strain) must be included in the generic name except where the submitter claims the taxonomic designation confidential, in which case the person making such claim must provide an explanation of why such masking is necessary to protect proprietary information. Additionally, the generic microorganism identity must include a statement regarding the function and stability of the genetic construct. This includes an indication of whether the introduced or modified genes are present on the chromosome or extrachromosomal.

(2) Generic names will be reviewed by EPA at the time of submission.

(i) If EPA concludes that a proposed generic name meets the criteria in paragraph (f)(1) of this section, EPA will include that generic name in the public TSCA Inventory listing for that substance.

(ii) If the proposed generic name does not meet the criteria in paragraph (f)(1) of this section, EPA will notify the submitter concerning the deficiency via CDX, as described in § 703.5(h) of this subchapter. EPA will provide ten business days to correct the deficiency and provide an alternative generic name that would be acceptable to EPA. If the alternative generic name proposed by EPA is acceptable to the submitter (or if

the submitter does not respond within the ten-day period), EPA will place that alternative generic name on the public TSCA Inventory. If the alternative generic name proposed by EPA is not acceptable to the submitter, the submitter must submit a revised generic name that meets the criteria in paragraph (f)(1) of this section and an explanation of how EPA's proposed generic name reveals confidential information. If EPA concludes that the revised generic name also does not meet the criteria in paragraph (f)(1) of this section, EPA will hold the notice of commencement for a period of up to 10 business days. Reporting requirements will not be considered to have been met and the microorganism will not be added to the TSCA Inventory during this period. If the submission remains deficient after this 10-day period, EPA will proceed with CBI review of the microorganism identity claim and will likely deny the claim.

PART 790—PROCEDURES GOVERNING TESTING CONSENT AGREEMENTS AND TEST RULES

- 34. The authority citation for part 790 continues to read as follows:

Authority: 15 U.S.C. 2603.

- 32. Revise § 790.7 to read as follows:

§ 790.7 Confidentiality.

Claims of confidentiality must be made in accordance with the procedures described in 40 CFR part 703.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Centers for Medicare & Medicaid Services**

42 CFR Parts 417, 422, 423, 455, and 460

[CMS–4201–CN2]

RIN 0938–AU96

Medicare Program; Contract Year 2024 Policy and Technical Changes to the Medicare Advantage Program, Medicare Prescription Drug Benefit Program, Medicare Cost Plan Program, and Programs of All-Inclusive Care for the Elderly; Correction

AGENCY: Centers for Medicare & Medicaid Services (CMS), HHS.

ACTION: Final rule; correction.

SUMMARY: This document corrects technical errors that appeared in the