9606, 9607, 9621. In CERCLA, Congress explicitly provided that in remedial actions, the clean-up level for groundwater must be that ''which at least attains Maximum Contaminant Level Goals established under [SDWA] and water quality criteria established under . . . the Clean Water Act'' where such goals or criteria are relevant and appropriate under the circumstances of the release or potential release.'' *Id.* § 9621(d)(2)(A). EPA's National Contingency Plan regulations implementing CERCLA also provide that ''EPA expects to return usable ground waters to their beneficial uses wherever practicable, within a timeframe that is reasonable given the particular circumstances of the site.'' 40 CFR 300.430(a)(1)(iii)(F). The determination of a ''beneficial use'' of groundwater is tied to state and local classifications (unless the state classification is less stringent than the EPA classification scheme), evidencing EPA's recognition of the state-specific nature of groundwater regulation. *See* Preamble to the National Contingency Plan, 55 FR 8733 (Mar. 8, 1990).

Finally, as the Agency has recognized, ''CERCLA cleanup levels are designed to address all reasonably anticipated routes of exposure that may pose an actual or potential risk to human health or the environment.'' EPA Office of Solid Waste and Emergency Response Directive 9283.1–33 at 9. These routes of exposure include ''groundwaters as a source of contamination to other media'' including intrusion into surface waters. *Id.* In determining clean-up standards, CERCLA and the National Contingency Plan require the identification of ''applicable or relevant and appropriate requirements,'' 42 U.S.C. 9621(d); 40 CFR 300.400(g), which, for remedying discharges to groundwater that reaching surface water, could include CWA requirements that are specifically addressed at the receiving surface water. *See* Directive 9283.1–33 at 8 (''Where groundwaters may impact surface water quality, water quality criteria under sections 304 or 303 of the Clean Water Act, may be relevant and appropriate standards[.]''). Thus, both CERCLA and EPA's regulations and guidance clearly address and provide for remediation of not only discharges to groundwater, but specifically impacts to surface water from polluted groundwater.

Dated: April 12, 2019.

David P. Ross,

Assistant Administrator, Office of Water.

[FR Doc. 2019–08063 Filed 4–22–19; 8:45 am]

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA–HQ–OPPT–2018–0320; FRL–9992–05]

RIN 2070–AK21

Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The 2016 amendments to the Toxic Substances Control Act (TSCA) require EPA to establish a plan to review all confidential business information (CBI) claims for specific chemical identity asserted in a Notice of Activity (NOA) Form A. EPA is proposing a rule to establish the plan, including the procedures for substantiating and reviewing these claims.

DATES: Comments must be received on or before June 24, 2019.

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA–HQ–OPPT–2018–0320, by one of the following methods.

- *Federal eRulemaking Portal: https://www.regulations.gov*. Follow the online instructions for submitting comments. Do not submit electronically any information you consider to be Confidential Business Information (CBI) or other information whose disclosure is restricted by statute.
- *Mail:* Document Control Office (7407M), Office of Pollution Prevention and Toxics (OPPT), Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001.
- *Hand Delivery:* To make special arrangements for hand delivery or delivery of boxed information, please follow the instructions at *https://www.epa.gov/dockets/where-send-comments-epa-dockets.* Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at *https://www.epa.gov/dockets.*

FOR FURTHER INFORMATION CONTACT: *For technical information contact:* Scott M. Sherlock, Environmental Assistance Division (Mail code 7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave. NW, Washington, DC 20460–0001; telephone number: (202) 564–8257; email address: *sherlock.scott@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 reported a confidential chemical substance under the TSCA Inventory Notification (Active-Inactive) Requirements rule (hereinafter ''Active-Inactive rule'') (Ref. 1) (40 CFR part 710, subpart B) through a Notice of Activity (NOA) Form A (Ref. 2) and sought to maintain an existing CBI claim for a specific chemical identity. The following North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

- Chemical manufacturing or processing (NAICS code 325).
- Petroleum and Coal Products Manufacturing (NAICS code 324).

The discussion in Unit III.A. and the proposed regulatory text describe in more detail the circumstances in which entities might be subject to this proposed action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical person listed under **FOR FURTHER INFORMATION CONTACT**.

Note that TSCA's statutory definition of ''manufacture'' includes importing. Accordingly, the regulatory definition of ''manufacture'' for this rule includes importation. Since ''manufacture'' is itself defined at 40 CFR 710.3(d) and at TSCA section 3(9) (15 U.S.C. 2602(9)) to include ''import,'' it is clear that importers are a subset of manufacturers. All references to manufacturing in this document should be understood to also encompass importing. Where EPA's intent is to specifically refer to domestic manufacturing or importing (both activities constitute ''manufacture''), this rule will do so expressly.

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

EPA is proposing this rule pursuant to the authority in TSCA section 8(b), 15 U.S.C. 2607(b). See also the discussion in Unit II.B.

In addition, the Paperwork Reduction Act (PRA), 44 U.S.C. 3501 *et seq.,* requires Federal agencies to manage information resources to reduce information collection burdens on the public (including through the use of automated collection techniques or other forms of information technology);

increase program efficiency and effectiveness; and improve the integrity, quality, and utility of information to all users within and outside an agency, including capabilities for ensuring dissemination of public information, public access to Federal Government information, and protections for privacy and security (44 U.S.C. 3506).

TSCA section 2 expresses the intent of Congress that EPA carry out TSCA in a reasonable and prudent manner and in consideration of the impacts that any action taken under TSCA may have on the environment, the economy, and society. EPA is proposing to manage and leverage its information resources, including information technology, to require the use of electronic reporting to implement this proposed rulemaking in a reasonable and prudent manner.

C. What action is the agency taking?

Pursuant to TSCA sections 8(b)(4)(C) through (E), EPA is proposing to amend 40 CFR part 710 to establish a new subpart C that sets forth the Agency's plan to review certain CBI claims to protect the specific chemical identities of substances on the confidential portion of the TSCA Inventory. The CBI claims that would be reviewed under this plan are those that were asserted on NOA Form A's filed in accordance with the requirements in the Active-Inactive rule (40 CFR part 710, subpart B).

In accordance with TSCA section 8(b)(4)(D), EPA is proposing substantiation requirements for manufacturers (including importers) and processors who filed NOA Form A's with assertions that they seek to maintain CBI claims to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory. Manufacturers and processors who provided substantiations pursuant to the voluntary substantiation process in the Active-Inactive rule NOA collection, or who identify a previous substantiation for the claim made to EPA during the 5-year period ending on the substantiation deadline specified by EPA, would be exempt from this requirement. EPA would review each specific chemical identity CBI claim and substantiation, and approve or deny each claim consistent with the procedures and substantive criteria in TSCA sections 8(b)(4) and 14 and 40 CFR part 2, subpart B. Also included in this proposed rule are provisions clarifying the duration of protection for approved CBI claims, and providing for the publication of annual review goals and results.

As described in Unit III.D., EPA is proposing to apply the electronic reporting requirement at 40 CFR 710.39 to the substantiation requirements of the CBI review plan. The Agency is proposing to require submitters to use EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, for reporting information.

D. Why is the agency taking this action?

TSCA section 8(b)(4)(C) requires EPA to promulgate a rule that establishes a plan to review all CBI claims to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory that were asserted in an NOA Form A pursuant to the Active-Inactive rule. This proposed rule is a follow-on regulation to the Active-Inactive rule that would require substantiation of CBI claims for specific chemical identity from any reporters who asserted such a claim as part of the NOA Form A submission, but did not provide (voluntary) upfront substantiation at that time. TSCA section 8(b)(4)(C) further requires EPA to promulgate this rule not later than one year after the date that the Agency published the first TSCA Inventory containing all ''active'' substance designations. EPA announced the release of the updated TSCA Inventory on February 19, 2019. To download the public version of the TSCA Inventory, get more information about the TSCA Inventory Notification (Active-Inactive) Requirements rule, or requirements to notify EPA going forward, go to *https://www.epa.gov/tsca-inventory*.

E. What are the estimated incremental impacts of this action?

EPA has evaluated the potential costs of establishing the proposed reporting requirements for manufacturers and processors. An economic analysis titled ''Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory'' has been prepared for the proposed rule, is available in the docket, and is briefly summarized here (Ref. 3). The proposed rule requirements involve a one-time reporting effort with activities that are the same, or similar to those in the Active-Inactive rule. All respondents would already have submitted at least one NOA under the Active-Inactive rule, and therefore should know whether any actions are necessary under this proposed rule. Moreover, an exemption included in this proposed rule would allow certain submitters to reference a previously submitted chemical identity CBI substantiation (in the last five years), in lieu of providing a full CBI substantiation for the NOA Form A chemical identity information.

Companies potentially affected by this proposed rule fall into three groups of potential NOA Form A reporters who made a CBI claim for a specific chemical identity. The first group (Group (1)) consists of those reporters who already voluntarily submitted upfront CBI substantiation as part of the NOA submission process, who therefore do not need to take further action. The second group (Group (2)) consists of those reporters who will be able to use the exemption offered under this proposed rule by referencing a previous substantiation, such as one submitted through the 2016 Chemical Data Reporting (CDR) rule (40 CFR part 711). The third group (Group (3)) consists of the remaining reporters who did not submit prior chemical identity CBI substantiations and would be required to provide full substantiation as proposed in this rule. The average incremental burden and cost estimates include rule familiarization, recordkeeping and submission of applicable CBI substantiations (*i.e.,* one-time form completion). For Group (1), the burden and costs for this group are minimal and were not calculated because the reporters have already voluntarily submitted upfront CBI substantiation as part of the NOA submission process for the Active-Inactive rule and would not need to take further action. For Group (2), the average burden and costs per company are estimated at 5.1 hours and $390, respectively per submission (involving on average four chemicals per company), for rule familiarization and substantiation using a previous reference. For Group (3), the average burden and costs per company are estimated at 34.1 hours, and $2,641 respectively per submission (involving on average 27 chemicals per company), for rule familiarization and full substantiation. An estimated 126 companies would be expected to report, with an estimated 23 companies in Group (2), and 103 companies in Group (3), resulting in an estimated total incremental burden and costs expected over 60 days of 3,629 hours and $280,981 for this proposed rule (Ref. 3).

F. What should I consider as I prepare my comments for EPA?

1. Submitting CBI. Do not submit this information to EPA through regulations.gov or email. Clearly mark the part or all of the information that you claim to be CBI. For CBI in a CD–ROM or other electronic media that you mail to EPA, mark the outside of the media as CBI and then identify electronically within the media the specific information that is claimed as

CBI. In addition to one complete version of the comment that includes information claimed as CBI, a copy of the comment that does not contain the information claimed as CBI must be submitted for inclusion in the public docket. Information so marked will not be disclosed except in accordance with procedures set forth in 40 CFR part 2, subpart B.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at *https://www.epa.gov/dockets/commenting-epa-dockets.html*.

II. Background

A. The TSCA Inventory and Active-Inactive Rule

EPA is required under TSCA section 8(b) to compile and keep current a list of chemical substances manufactured or processed in the United States. This list, the TSCA Chemical Substance Inventory (TSCA Inventory), is EPA's comprehensive list of confidential and non-confidential substances manufactured or processed in the United States for nonexempt commercial purposes (Ref. 4). EPA promulgated the Active-Inactive rule to obtain the information necessary for EPA to designate as ''active'' chemical substances that had been manufactured or processed for a nonexempt commercial purpose during the 10-year time period ending on June 21, 2016. Respondents (manufacturers and processors) reported these chemical substances through the process set forth in 40 CFR part 710, subpart B, by filing an NOA Form A with EPA. Consistent with TSCA section 8(b)(4)(B)(ii), respondents who manufactured or processed an active chemical substance listed on the confidential portion of the TSCA Inventory prior to June 22, 2016, could seek to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential by voluntarily filing an NOA Form A that included such request. Through this process established in 40 CFR 710.37(a), manufacturers and processors secured an opportunity to maintain the confidential status of a specific chemical identity on the confidential portion of the TSCA Inventory.

B. Statutory Requirements for the CBI Review Plan

TSCA section 8(b)(4)(C) requires EPA to promulgate a rule establishing a plan to review all CBI claims to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory that were asserted in an NOA Form A. TSCA requires that EPA promulgate this rule not later than one year after the publication of the first TSCA Inventory containing all ''active'' substance designations (TSCA section 8(b)(4)(C)). TSCA also requires the Agency to implement the CBI review plan so as to complete all CBI claim reviews not later than five years after such TSCA Inventory publication, with the possibility of a two-year extension (TSCA section 8(b)(4)(E)). Since the updated TSCA Inventory was released on February 19, 2019, the deadline for issuing a final rule is February 19, 2020, and the deadline for completing all the CBI claim reviews is February 19, 2024. If EPA determines in the future to invoke the 2-year extension under TSCA, the deadline for completing all the CBI claim reviews would then become February 19, 2026.

Other types of CBI claims are outside the scope of the review plan under TSCA section 8(b)(4)(C) through (E), and hence are outside the scope of this proposed rule. Those claims are governed by other statutory and regulatory provisions. Substantiation and review of CBI claims for other data elements in an NOA Form A are governed by TSCA section 14(g) and 40 CFR 710.37(b) and (c)(1). Substantiation and review of CBI claims for specific chemical identity in an NOA Form B—a forward-looking reporting form required when reintroducing an ''inactive'' chemical substance into U.S. commerce for a nonexempt commercial purpose—are governed by TSCA section 8(b)(5) and 40 CFR 710.37(a)(2).

TSCA section 8(b)(4)(D) provides the parameters of the review plan for specific chemical identity CBI claims asserted in NOA Form A's.

1. Requirement to provide substantiations. TSCA section 8(b)(4)(D)(i) provides that in establishing the review plan, EPA must require all manufacturers and processors to substantiate their CBI claims for specific chemical identities in accordance with TSCA section 14 and at a time specified by EPA, unless the manufacturer or processor has previously substantiated the claim in a submission made to EPA during the 5-year period ending on the substantiation deadline specified by EPA.

2. EPA review of confidentiality claims and substantiations. TSCA section 8(b)(4)(D)(ii) requires that EPA review each CBI claim and substantiation for a specific chemical identity to determine if such claim qualifies for protection from disclosure. The Agency must then approve or deny each claim. TSCA section 8(b)(4)(D)(ii)(III) further provides that if the information is approved for CBI status, then, except as otherwise provided in TSCA sections 8 and 14, EPA must protect such information from disclosure for a period of 10 years, unless the claim is withdrawn, or EPA becomes aware that the information does not qualify for protection from disclosure, in which latter case EPA must take the actions described in TSCA section 14(g)(2) (*i.e.,* to notify the claimant of EPA's intent to disclose the information).

3. Completion of reviews. TSCA section 8(b)(4)(E) provides that the Agency must implement the review plan so as to complete all of the reviews not later than five years after the date on which the Agency has compiled the initial list of active substances. With adequate public justification, the Agency may extend the deadline for completion of reviews for not more than two years.

4. Posting of annual goals and numbers of reviews completed. TSCA section 8(b)(4)(E) further requires that at the beginning of each year, EPA publish an annual goal for reviews and the number of reviews completed in the prior year.

5. Record retention requirement. TSCA section 8(b)(9)(B) provides that records relevant to compliance with this rule must be retained for a period of 5 years beginning on the last day of the submission period.

III. Summary of Proposed Rule

The TSCA section 8(b)(4)(D) and (E) provisions regarding the Review Plan are prescriptive and the proposed rule closely follows the statutory text.

A. What confidentiality claims for specific chemical identities would be substantiated under this rule?

1. CBI claims subject to substantiation. Subject to the exemptions described in this unit, the substantiation requirement in this proposed rule would apply to all CBI claims for specific chemical identities that manufacturers or processors requested to maintain in NOA Form A's filed in accordance with the Active-Inactive rule.

2. Exemptions from substantiation requirement. Pursuant to TSCA section 8(b)(4)(D), EPA is proposing exemptions from the requirement to submit new substantiation in certain cases where the CBI claims have already been substantiated in a recent submission to EPA. The proposed exemptions would be available to manufacturers or processors who provided substantiations for specific chemical

identity CBI claims either: (1) Pursuant to the voluntary substantiation process associated with the Active-Inactive rule, or (2) in another submission made to EPA less than five years before the substantiation deadline that will be set in the final rule.

For those manufacturers or processors who filed voluntary substantiations with their NOA Form A's pursuant to the process set forth in the Active-Inactive rule, codified at 40 CFR 710.37(a)(1), no further action would be required. Those persons would automatically be deemed exempt from the substantiation requirement under this proposed rule.

EPA is proposing to require manufacturers and processors who wish to establish eligibility for an exemption based upon any other recently-submitted substantiation to report and identify for EPA the following about that recently-submitted substantiation: Submission date; submission type; and case number, transaction ID, or equivalent identifier that uniquely identifies the previous submission that includes the substantiation upon which the manufacturer or processor is relying.

Previously submitted substantiations might include, for example, those submitted pursuant to a regulatory up-front substantiation requirement (such as 40 CFR 711.30(b)(1) or 40 CFR 720.85(b)(3)(iv)), the statutory substantiation requirement at TSCA section 14(c)(3) (see 82 FR 6522, January 19, 2017), or the comment process described in 40 CFR 2.204(e).

B. When would substantiation be required?

EPA is proposing to require that all substantiations be filed not later than 90 days after the effective date of the final rule. EPA is proposing the same filing deadline for submissions identifying a previously submitted substantiation for purposes of establishing eligibility for an exemption. If a substantiation or notice of prior CBI substantiation was not filed within the 90-day filing period in accordance with all requirements of this proposed rule or voluntarily filed in accordance with all requirements of 40 CFR 710.37(a)(1), EPA is proposing to consider the confidentiality claim to be deficient and would treat the specific chemical identity as not subject to a confidentiality claim, such that EPA may make the information public without further notice. This treatment of unsubstantiated confidentiality claims as deficient would be consistent with how EPA has handled unsubstantiated confidentiality claims in other regulations, *e.g.,* 40 CFR 710.37(a)(2) and (b) (Active-Inactive rule) and 40 CFR 711.30(e) (Chemical Data Reporting rule). EPA nevertheless requests comment on the validity of making this information public without further notice, particularly where a claimant may have previously submitted a substantiation to EPA less than five years before the substantiation deadline that will be set in the final rule, but failed to report and identify that previously-submitted substantiation to EPA within the 90-day filing period.

C. How would CBI claims be substantiated?

EPA is proposing to require that non-exempt manufacturers and processors substantiate any CBI claim for a specific chemical identity that they requested to maintain in an NOA Form A by submitting answers to the questions identified in Unit III.C.1, by providing the certification statement identified in Unit III.C.2, and by requiring that the submission be signed and dated by an authorized official.

1. Substantiation questions. a. Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)? If you answered yes, you must individually identify the specific information claimed as confidential and specify the applicable exemption(s).

b. Will disclosure of the information likely result in substantial harm to your business's competitive position? If you answered yes, describe with specificity the substantial harmful effects that would likely result to your competitive position if the information is made available to the public.

c. To the extent your business has disclosed the information to others (both internally and externally), what precautions has your business taken? Identify the measures or internal controls your business has taken to protect the information claimed as confidential: Non-disclosure agreement required prior to access; access is limited to individuals with a need-to-know; information is physically secured; other internal control measure(s). If yes, explain.

d. Does the information appear in any public documents, including (but not limited to) safety data sheets, advertising or promotional material, professional or trade publication, or any other media or publications available to the general public? If you answered yes, explain why the information should be treated as confidential.

e. Is the claim of confidentiality intended to last less than 10 years? If so, indicate the number of years (between 1–10 years) or the specific date/occurrence after which the claim is withdrawn.

f. Has EPA, another federal agency, or court made any confidentiality determination regarding information associated with this chemical substance? If you answered yes, explain the outcome of that determination and provide a copy of the previous confidentiality determination or any other information that will assist in identifying the prior determination.

g. Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the United States? If you answered yes, explain why the information should be treated as confidential.

2. Certification Statement. An authorized official of a manufacturer or processor substantiating a request to maintain an existing claim of confidentiality for specific chemical identity would be required to certify that the submission complies with the requirements of the rule by signing and dating the following certification statement:

> ''I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. 1001. I further certify that it is true and correct that:
>
> • My company has taken reasonable measures to protect the confidentiality of the information;
>
> • I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law;
>
> • I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of my company; and
>
> • I have a reasonable basis to believe that the information is not readily discoverable through reverse engineering.''

D. How would information be submitted to EPA?

The proposed rule would require persons submitting substantiations or information on previously submitted substantiations to follow the electronic reporting procedures set forth in the Active-Inactive rule at 40 CFR 710.39. Any person submitting a substantiation under this proposed rule could claim any part or all of the substantiation as confidential business information. Submitters would be required to use EPA's electronic reporting portal, Central Data Exchange (CDX), and EPA's web-based reporting tool, Chemical Information Submission System (CISS). Because all submitters under this proposed rule would have previously

filed NOA Form A's under the Active-Inactive rule using these electronic reporting procedures, EPA expects that all submitters are already registered with CDX and familiar with the electronic reporting procedures. EPA is proposing mandatory electronic reporting because it is expected to allow for more efficient data transmittal, support improved data quality, and minimize respondent burden and reduce EPA administrative costs associated with information submission and recordkeeping.

E. How would EPA review claims of confidentiality for specific chemical identities?

Consistent with how EPA handles the review of other TSCA confidentiality claims, EPA would carefully consider the facts provided in the substantiations, any pertinent previously issued confidentiality determinations, and other reasonably available information that EPA finds appropriate to determine the information's entitlement to confidential treatment. *See* 40 CFR 2.204(f), 2.205(d)(2) and 2.306. EPA would apply the substantive criteria for confidentiality determinations set forth in 40 CFR 2.208 and 2.306(g), which provide in relevant part that information is entitled to confidential treatment for the benefit of a particular business if: (a) The business has asserted a confidentiality claim which has not expired by its terms, nor been waived nor withdrawn; (b) 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; (c) 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 need in a judicial or quasi-judicial proceeding); (d) no statute specifically requires disclosure of the information; and (e) the business has satisfactorily shown that disclosure of the information is likely to cause substantial harm to the business's competitive position.

In instances where there are multiple NOA Form A's asserting the confidentiality of the same chemical identity, the Agency may choose to review these NOA Form A's together as a matter of efficiency.

In instances where a CBI claim is denied, the Agency would notify the submitter, in writing, of EPA's intent to disclose the specific chemical identity and of EPA's reasons for denying the claim. The notice would be furnished by certified mail (return receipt requested), by personal delivery, or by other means that allows verification of the fact and date of receipt. EPA would not disclose the specific chemical identity until the date that is 30 days after the date on which the submitter receives the denial notice. Submitters can challenge EPA's denial of a CBI claim by commencing an action to prevent disclosure in an appropriate Federal district court. See generally TSCA section 14(g) and 40 CFR 2.306(e). In instances where a CBI claim is approved, EPA would so inform the submitter, and the chemical substance will be identified in subsequent publications of the TSCA Inventory by a unique identifier assigned under TSCA section 14(g)(4), in addition to the accession number, generic name, and, if applicable, premanufacture notice case number. Further information about the assignment and application of unique identifiers for confidential chemical substances may be found in the **Federal Register** of June 27, 2018 (83 FR 30168).

F. Annual Review Goals and Results, Extension

EPA is proposing to use the Agency's website to publish its annual goal for reviews completed under this review plan at the beginning of each calendar year, starting with its goals for 2020, which the Agency anticipates would be posted in February 2020 on the Agency web page. EPA is also proposing to track the number of CBI reviews completed under this review plan each year and is proposing to use the Agency's website to publish that number at the beginning of the following year, starting with the number of reviews completed in 2020, which the Agency anticipates would be posted on the Agency web page in February 2021. These activities will address the requirements of TSCA section 8(b)(4)(E)(ii)(II).

EPA intends to implement the CBI review plan described in this proposed rule to complete reviews of all CBI claims for specific chemical identities not later than five years after the publication of the first TSCA Inventory containing all ''active'' substance designations based on NOA Form A's, as required under TSCA section 8(b)(4)(E)(i). Since the initial list of active substances published on February 19, 2019, EPA intends to complete all reviews by February 19, 2024. EPA intends the annual review goals to take into consideration this target completion date, the number of claims needing review, and available resources. Before the effective date of this rule's finalization, EPA may begin reviewing and deciding claims that were voluntarily substantiated under the Active-Inactive rule (subject to the outcome of pending litigation involving that rule), or that appear to be clearly not entitled to protection from disclosure based upon other information available to the Agency. TSCA section 14(i)(2) expressly permits EPA to review, require (re)substantiation of, and decide TSCA CBI claims before the effective date of such rules applicable to those claims as EPA may promulgate after June 22, 2016. EPA believes that TSCA section 14(i)(2) clearly authorizes the Agency to begin its reviews under TSCA section 8(b)(4) prior to publication of this final rule, and that doing so is appropriate in light of the Congressionally-mandated timeline for the completion of reviews.

TSCA section 8(b)(4)(E)(ii)(I) provides that after an adequate public justification, the Agency may extend the five-year deadline for completion of reviews for not more than two additional years. While the Agency does not currently anticipate a need for an extension, possible justifications for an extension might include, among other things, competing TSCA obligations which prevent the Agency from completing the reviews within five years, intervening events that divert the Agency's resources from completing the required reviews, or litigation involving the claim substantiation and review process that may delay EPA's commencement of CBI claim reviews. Should an extension become necessary, EPA is proposing to announce the extension and its justification to the public via a notice in the **Federal Register**.

G. Duration of Protection From Disclosure

TSCA section 8(b)(4)(D)(ii)(III) provides that specific chemical identities for which EPA has approved a CBI claim under TSCA section 8(b)(4)(D) must be protected from disclosure for a period of 10 years, unless, prior to the expiration of that period, the claimant notifies EPA that they are withdrawing the confidentiality claim, in which case the Agency cannot protect the information from disclosure; or the Agency otherwise becomes aware that the information does not qualify for protection from disclosure, in which case the Agency must take the actions described in TSCA section 14(g)(2) (*i.e.,* to notify the claimant of EPA's intent to disclose the information). TSCA section 8(b)(4)(D)(ii)(III) does not explicitly state when the 10-year period of protection begins, but TSCA section 8(b)(4)(D)(ii) provides as a general matter that EPA's

actions under the review plan must be ''in accordance with section 14.'' Under TSCA section 14(e)(1)(B)(i), as amended on June 22, 2016, the duration of protection from disclosure lasts ''for a period of 10 years from the date on which the person asserts the claim with respect to the information submitted to the Administrator.''

Notably, all specific chemical identity CBI claims subject to review under TSCA section 8(b)(4) and this proposed rule had already been asserted by one or more persons prior to June 22, 2016, resulting in the placement of the chemical substance on the confidential portion of the TSCA Inventory. Pursuant to TSCA section 8(b)(4)(B)(ii) and the Active-Inactive rule, manufacturers and processors submitting NOA Form A's were only permitted to indicate that they seek to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance. TSCA section 8(b)(4)(C) describes these requests to maintain existing claims as ''*claims . . . asserted* pursuant to [TSCA section 8(b)(4)(B)],'' and TSCA section 8(b)(4)(D)(i) refers to ''manufacturers or processors *asserting claims* under [TSCA section 8(b)(4)(B)]'' (emphasis added). Thus, EPA believes Congress intended that the filing date of the request seeking to maintain the CBI claim (*i.e.,* the filing date of the NOA Form A) may function as the date of claim assertion for purposes of determining the period of protection from disclosure. However, in cases where the same specific chemical identity was subject to a CBI claim in another submission filed on or after June 22, 2016, EPA believes it would be incongruous to effectively re-start the 10-year period of protection from disclosure based upon the subsequent submission of a request (*i.e.,* an NOA Form A) seeking to maintain that claim. Accordingly, EPA proposes to interpret the date of assertion for purposes of calculating the duration of protection under TSCA section 8(b)(4)(D)(ii)(III) as the date of submission of the first filing in which the specific chemical identity was claimed as CBI after June 22, 2016. This interpretation would impact the calculation of the period of protection from disclosure where there are multiple submitters of the NOA Form A that are asserting confidentiality claims on the same specific chemical identity, as well as where one or more submitters of information to EPA outside the context of the NOA Form A has asserted a specific chemical identity confidentiality claim after June 22, 2016. Companies will be notified of the date from which the 10-year period of protection will be calculated.

For example, if on July 1, 2016, a company addressing a CDR rule reporting requirement filed a report for a subject chemical substance and asserted a CBI claim for the specific chemical identity, and if EPA subsequently approved the company's confidentiality claim, then the 10-year time period of protection from disclosure would begin on July 1, 2016. If that company subsequently filed an NOA Form A on January 1, 2018 and sought to maintain the confidentiality claim for that specific chemical identity, and if EPA subsequently approved that claim, the 10-year period of protection from disclosure would continue to run from July 1, 2016, and would not restart on the date of NOA filing. If a second company then filed an NOA Form A on February 1, 2018 seeking to maintain a CBI claim for that same specific chemical identity, and the second company's claim were approved, the 10-year period of protection from disclosure would still run from July 1, 2016. In cases where an NOA Form A was the first submission to assert the CBI claim for a specific chemical identity after June 22, 2016, the 10-year period of protection for an approved claim would begin on the date of that NOA filing.

H. What are the record retention requirements?

EPA is proposing to require that persons subject to the finalized rule retain records that document any information reported to EPA. The proposed rule would require such records to be retained for a period of 5 years beginning on the last day of the submission period, which is consistent with the statutory mandate in TSCA section 8(b)(9)(B).

IV. Request for Comments

EPA is seeking public comment on all aspects of this proposed rule, including filing requirements, the exemptions process, annual goal setting, duration of protection from disclosure, Agency reviews, economic burden, and the scope of the substantiation questions described in Unit III.C and referenced in the proposed regulatory text at section 710.45, as well as other issues discussed in this document.

V. References

The following is a listing of the documents that are specifically referenced in this document. The docket includes these references 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 technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. TSCA Inventory Notification (Active-Inactive) Requirements Rule. **Federal Register**, 82 FR 37520, August 11, 2017 (FRL–9964–22).

2. EPA. Notice of Activity Form A; Final, 2017.

3. EPA. *Economic Analysis for the Proposed Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory*—RIN 2070–AK21—Office of Pollution Protection and Toxics. Washington, DC, February 2019.

4. EPA. TSCA Chemical Substance Inventory. 2018. *https://www.epa.gov/tsca-inventory/how-access-tsca-inventory*.

5. EPA. ICR No. 2594.01 *Information Collection Request for* TSCA Review Plan CBI Substantiation *Supporting Statement for a Request for OMB Review under the Paperwork Reduction Act*. February 2019.

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*.

A. Executive Order 12866: Regulatory Planning and Review and Executive Order 13563: Improving Regulation and Regulatory Review.

This action is a significant regulatory action that was submitted to the Office of Management and Budget (OMB) for review under Executive Orders 12866 (58 FR 51735, October 4, 1993) and 13563 (76 FR 3821, January 21, 2011). Any changes made in response to OMB recommendations have been documented in the docket for this action as required by section 6(a)(3)(E) of Executive Order 12866.

B. Executive Order 13771: Reducing Regulations and Controlling Regulatory Costs

This action is expected to be subject to the requirements for regulatory actions specified in Executive Order 13771 (82 FR 9339, February 3, 2017). EPA prepared an analysis of the estimated costs and benefits associated with this action (Economic Analysis, Ref. 3), which is available in the docket and is summarized in Unit I.E.

C. Paperwork Reduction Act (PRA)

The information collection activities in this proposed rule have been submitted for approval to the Office of Management and Budget (OMB) under the PRA, 44 U.S.C. 3501 *et seq.* The Information Collection Request (ICR)

document that the EPA prepared has been assigned EPA ICR number ICR No. 2594.01 and OMB Control No. 2070–NEW (Ref. 5). You can find a copy of the ICR in the docket for this rule, and it is briefly summarized here.

The reporting requirements identified in the proposed rule would provide EPA with information necessary to evaluate confidentiality claims and determine whether the claims qualify for protection from disclosure. Manufacturers and processors who provided substantiations pursuant to the voluntary substantiation process in the Active-Inactive rule NOA collection would be exempt from the proposed substantiation requirements. EPA would review each specific chemical identity CBI claim and substantiation, and approve or deny each claim consistent with the procedures and substantive criteria in TSCA sections 8(b)(4) and 14 and 40 CFR part 2, subpart B.

Respondent's obligation to respond: Mandatory.

Frequency of response: Once per chemical.

Estimated total number of potential respondents: 126.

Estimated total burden: 3,629 hours (one time). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: $ 280,981 (one time), includes no annualized capital investment or maintenance and operational costs.

Under PRA, 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 are displayed either by publication in the **Federal Register** or by other appropriate means, such as on the related collection instrument or form, if applicable. The display of OMB control numbers for certain EPA regulations is consolidated in 40 CFR part 9.

Submit your comments on the Agency's need for this information, the accuracy of the provided burden estimates and any suggested methods for minimizing respondent burden to EPA using the docket identified at the beginning of this proposed rule. You may also send your ICR-related comments to OMB's Office of Information and Regulatory Affairs via email to *OIRA_submission@omb.eop.gov,* Attention: Desk Officer for EPA. Since OMB is required to make a decision concerning the ICR between 30 and 60 days after receipt, OMB must receive comments no later than May 23, 2019. EPA will respond to any ICR-related comments in the final rule.

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.,* I certify that this action will not have a significant economic impact on a substantial number of small entities. The small entities subject to the requirements of this action are manufacturers (including importers) and processors of chemical substances. EPA estimates that a total of 126 companies are expected to be impacted by this proposed rule, of which 121 are identified as small entities. Given the estimated per submission burden and costs range from 5.1 hours and $390 (for Group (2)) to 34.1 hours and $ 2,640 (for Group (3)), as presented in Unit 1.E. EPA has determined that all 121 of the identified small entities considered in this analysis will experience an impact of less than 1% of revenues.

In the affected universe of small entities, there are two groups of entities affected by this proposed rule (Groups (2) and (3)), based on the extent of substantiation information involved in the submission. Entities of Group (3) are expected to incur the highest burden under this proposed rule, as they are required to submit full confidentiality substantiations (each submission involving an average of 27 chemicals per entity) in response to the regulatory requirements. As a conservative approach, in this small entity analysis the higher unit cost from Group (3), as the most affected group, is applied to all small entities. Details of this analysis are included in the accompanying Economic Analysis for this proposed rule (Ref. 3).

E. 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 is not expected to impose enforceable duty on any state, local or tribal governments, and the requirements imposed on the private sector are not expected to result in annual expenditures of $100 million or more for the private sector. As such, EPA has determined that the requirements of UMRA sections 202, 203, 204, or 205 do not apply to this action.

F. Executive Order 13132: Federalism

This action does not have federalism implications as specified in Executive Order 13132 (64 FR 43255, August 10, 1999). 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.

G. 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). 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. Thus, E.O. 13175 does not apply to this action.

H. 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 health or safety risks, such that the analysis required under section 5–501 of Executive Order 13045 has the potential to influence the regulation. This action is not subject to Executive Order 13045 because it does not establish an environmental standard intended to mitigate health or safety risks.

I. Executive Order 13211: Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use

This action is not a ''significant energy action'' as defined in Executive Order 13211 (66 FR 28355, May 22, 2001), because it is not likely to have a significant adverse effect on energy supply, distribution, or use.

J. National Technology Transfer and Advancement Act (NTTAA)

Since this action does not involve any technical standards, NTTAA section 12(d), 15 U.S.C. 272 note, does not apply to this action.

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

This action does not entail special considerations of environmental justice related issues as delineated by Executive Order 12898 (59 FR 7629, February 16, 1994), because it does not establish an environmental health or safety standard. This action establishes an information requirement and does not affect the level of protection provided to human health or the environment.

List of Subjects in 40 CFR Part 710

Environmental Protection, Chemicals, Confidential Business Information, Hazardous substances, Reporting and Recordkeeping Requirements.

Dated: April 10, 2019.

Andrew R. Wheeler,

Administrator.

Therefore, it is proposed that 40 CFR chapter I be amended as follows:

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

■ 1. The authority citation for part 710 continues to read as follows:

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

■ 2. Add subpart C to read as follows:

Subpart C—Review Plan

Sec.

§ 710.41 Scope.

This part applies to the substantiation and review of claims of confidentiality asserted in Notices of Activity Form A to protect the specific chemical identities of chemical substances.

§ 710.43 Persons subject to substantiation requirement.

(a) Any person who filed a Notice of Activity Form A requesting to maintain an existing confidentiality claim for a specific chemical identity must substantiate that confidentiality claim as specified in §§ 710.45 and 710.47 unless eligible for an exemption.

(b) *Exemptions.* (1) Any person who completed the voluntary substantiation process set forth in § 710.37(a)(1) by submitting with the Notice of Activity Form A answers to the questions in § 710.37(c)(1) and (2), signed and dated by an authorized official, and completing the certification statement for claims specified in § 710.37(e), is exempt from the substantiation requirement of this subpart.

(2) A person who has previously substantiated the confidentiality claim for a specific chemical identity that the person requested to maintain in a Notice of Activity Form A is exempt from the substantiation requirement of this subpart if both of the following conditions are met:

(i) The previous substantiation was submitted to EPA on or after [insert date five years before the date that is 90 days after effective date of final rule]; and

(ii) The person reports to EPA the submission date; submission type; and case number, transaction ID, or equivalent identifier for the previous submission that contained the substantiation, not later than the deadline specified in § 710.47.

§ 710.45 Contents of substantiation.

A person substantiating a confidentiality claim for a specific chemical identity must submit answers to the questions in § 710.37(c)(1) and (2), signed and dated by an authorized official, and complete the certification statement in § 710.37(e). If any of the information contained in the answers to the questions listed in § 710.37(c)(1) or (2) is claimed as confidential, the submitter must clearly indicate such by marking the substantiation as confidential business information.

§ 710.47 When to submit substantiation or information on previous substantiation.

(a) All persons required to substantiate a confidentiality claim pursuant to § 710.43(a) must submit their substantiation not later than [insert date that is 90 days after effective date of final rule].

(b) All persons who seek an exemption under § 710.43(b)(2) must submit the information specified in § 710.43(b)(2)(iii) not later than [date that is 90 days after effective date of final rule].

§ 710.49 No confidentiality claim.

If substantiation required under § 710.43(a) is not submitted to EPA in accordance with the provisions of this subpart, and no exemption under § 710.43(b) applies, EPA will consider the confidentiality claim as deficient, so that the specific chemical identity is not subject to a confidentiality claim, and EPA may make the information public without further notice to the Notice of Activity Form A submitter.

§ 710.51 Electronic filing.

EPA will accept information submitted under this subpart only if submitted in accordance with § 710.39.

§ 710.53 Record-keeping requirements.

Each person who is subject to this part must retain records that document any information reported to EPA. Records must be retained for a period of 5 years beginning on the last day of the submission period.

§ 710.55 Claim review, duration of protection, TSCA Inventory maintenance, posting results, and extension.

(a) *Review criteria and procedures.* Except as set forth in this subpart, confidentiality claims for specific chemical identities asserted in Notices of Activity Form A will be reviewed and approved or denied in accordance with the criteria and procedures in 40 CFR part 2, subpart B.

(b) *Duration of protection from disclosure.* Except as provided in 40 CFR part 2, subpart B, and section 14 of TSCA, a specific chemical identity that is the subject of an approved confidentiality claim under this subpart will be protected from disclosure for a period of 10 years from the date on which the confidentiality claim was first asserted by any submitter after June 22, 2016, unless, prior to the expiration of the period, the claimant notifies EPA that the person is withdrawing the confidentiality claim, in which case EPA will not protect the information from disclosure; or EPA otherwise becomes aware that the information does not qualify for protection from disclosure, in which case EPA will take the actions described in TSCA section 14(g)(2) to notify the claimant of EPA's intent to disclose the information.

(c) *Updating the TSCA Inventory.* EPA will periodically update the TSCA Inventory based on the results of the reviews of the confidentiality claims asserted in Notices of Activity Form A.

(d) *Posting of annual goals and numbers of reviews completed.* At the beginning of each calendar year, EPA will publish an annual goal for reviews and the number of reviews completed in the prior year on the Agency website. Determination of annual review goals will take into consideration the number of claims needing review, available resources, and a target completion date for all reviews under this subpart not later than February 19, 2024.

(e) *Extension.* If EPA determines that the target completion date in paragraph (d) of this section cannot be met based on the number of claims needing review and the available resources, then EPA will publish a document in the **Federal Register** announcing the extension of the deadline to complete its review of all confidentiality claims under this subpart for not more than two additional years, together with an explanation of the reasons for the extension.

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