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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2018-0320; FRL-10005-48]

RIN 2070-AK21

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

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is finalizing requirements for regulated entities to substantiate certain confidential business information (CBI) claims made under the Toxic Substances Control Act (TSCA) to protect the specific chemical identities of chemical substances on the confidential portion of the TSCA Inventory, and the Agency's plan for reviewing certain CBI claims for specific chemical identities. The substantiation requirements describe the applicable procedures and provide instructions for regulated entities. The Agency's plan sets out the review criteria and related procedures that EPA will use to complete the reviews within the five-year timeframe set in TSCA.

DATES: This final rule is effective on [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2018-0320, is available at <http://www.regulations.gov> or at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave., NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday

through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at <http://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. What action is the Agency taking?

This final rule establishes the CBI substantiation requirements for manufacturers (which under TSCA includes importers) and processors who claimed specific chemical identities as CBI in previously filed Notices of Activity (NOAs) Form A (Ref. 1) in accordance with the 2017 TSCA Inventory Notification (Active-Inactive) Requirements rule (hereinafter “2017 Active-Inactive Rule,” which is summarized in more detail in Unit III and codified in 40 CFR part 710, subpart B) (Ref. 2). This final rule also amends the existing CBI substantiation requirements for manufacturers and processors who have filed or will file NOAs Form B (Ref. 3) and claimed or claim specific chemical identities as CBI. Manufacturers and processors who previously provided substantiations in NOAs Form A or B for CBI claims for specific chemical identities

pursuant to the 2017 Active-Inactive Rule will be required to supplement those substantiations to include responses to two new questions related to a specific chemical identity's susceptibility to reverse engineering. All substantiations must be submitted to the Agency using EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal.

This final rule describes the Agency's plan to review the CBI claims for specific chemical identities that were asserted in NOAs Form A during the one-time retrospective reporting period under the 2017 Active-Inactive Rule, including procedures for the Agency's publication of annual review goals and results. EPA will 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.

EPA is amending the existing regulations in 40 CFR part 710, subpart B, and is adding provisions about the NOA Form A substantiation process and the Agency's review plan to a new subpart C.

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

EPA is issuing this rule pursuant to the authority in TSCA section 8(b), 15 U.S.C. 2607(b).

C. Why is the Agency taking this action?

TSCA section 8(b)(4)(C) requires EPA to promulgate a rule that establishes the Agency's plan to review all CBI claims for 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 one-time retrospective reporting under the 2017 Active-Inactive Rule. The 2017 Active-Inactive Rule required any reporter who sought to maintain an existing CBI claim for a specific chemical identity to assert that claim as part of the submission of an NOA Form A, but the rule

did not require substantiation of those claims at that time. This final rule implements the statutory substantiation and review requirements so as to ensure that only those specific chemical identities that currently qualify for confidential treatment are protected from disclosure by the Agency.

This final rule also addresses a Federal court remand of the 2017 Active-Inactive Rule by amending that rule to add two substantiation questions which will be applicable to all NOA Form B reporters who seek to maintain an existing CBI claim for a specific chemical identity, and by including the same two questions in the newly finalized substantiation requirements for NOA Form A reporters who seek to maintain an existing CBI claim for a specific chemical identity. These substantiation questions address whether a specific chemical identity is readily discoverable through reverse engineering and will ensure the submission of information that EPA will use to evaluate CBI claims for specific chemical identities.

D. Who does this action apply to?

You may be affected by this action if you reported a confidential chemical substance under the 2017 Active-Inactive Rule using an NOA Form A or NOA Form B and sought to maintain an existing CBI claim for a specific chemical identity. You may also be affected by this action if you anticipate reporting a confidential chemical substance under the 2017 Active-Inactive Rule through an NOA Form B in the future and anticipate seeking to maintain an existing CBI claim for a specific chemical identity at that time. The following North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provide 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).

“Manufacture” is defined in TSCA section 3(9) (15 U.S.C. 2602(9)) and 40 CFR 710.3(d) to include “import.” Accordingly, all references to manufacture in this document should be understood to include import.

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

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

EPA has evaluated the potential incremental impacts of this rulemaking in an economic analysis (EA), titled “Economic Analysis for the Final Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory” (Ref. 4), which is available in the docket, discussed in Unit IV., and briefly summarized here.

1. Benefits. The benefits of the rule include improvements in the management of CBI claims for specific chemical identities, including a decrease in the number of unsupported claims of confidentiality. There would also be a corresponding increase in transparency for the public with regard to specific chemical identity information. Overall, the rule results in a more efficient means of enacting the various requirements and duties prescribed to EPA in TSCA, while also providing the potential for a greater level of transparency with regard to the specific chemical identities of chemical substances on the TSCA Inventory.

2. Costs. Over the course of the first ten years after the effective date of the final rule, EPA estimates a one-time total burden and cost for regulated entities of 5,259 hours and approximately \$407,000, respectively and an ongoing, annual burden and cost of approximately 0.38 hours and \$29, respectively.

II. Background

A. How were CBI claims for specific chemical identities addressed in the 2017 Active-Inactive Rule?

Pursuant to TSCA section 8(b), the 2017 Active-Inactive Rule (codified in 40 CFR part 710, subpart B) required manufacturers, and allowed processors, to report those chemical substances on the TSCA Inventory that were manufactured or processed for a nonexempt commercial purpose during the 10-year time period ending on June 21, 2016. EPA used these retrospective notifications—filed on an NOA Form A—to designate chemical substances as “active” or “inactive,” and EPA now includes those active and inactive designations on the TSCA Inventory. Going forward, the 2017 Active-Inactive Rule requires notification if manufacturing or processing of an inactive chemical substance for a nonexempt commercial purpose is expected to resume. On receiving such a forward-looking notification—filed on an NOA Form B—EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. The one-time submission period for NOA Form A ended on October 5, 2018, while the NOA Form B is submitted on an ongoing basis.

Consistent with TSCA sections 8(b)(4)(B)(ii) and (5)(B)(ii), the 2017 Active-Inactive Rule provided that manufacturers and processors filing an NOA Form A or B could seek to maintain an existing CBI claim for a specific chemical identity by including such a request on their NOA Form A or B, through the process established in 40 CFR 710.37(a). NOA Form A submitters were permitted to voluntarily substantiate their CBI claims for specific chemical identities at the time of filing their NOA Form A by answering the substantiation questions set forth in 40 CFR 710.37(c). NOA Form B submitters were (and are, subject to the amendments effectuated through this rule) required to substantiate their CBI claims not later than 30 days after submitting their NOA Form B by answering the same substantiation questions.

On April 26, 2019, the U.S. Court of Appeals for the District of Columbia Circuit entered a judgment in *Environmental Defense Fund v. EPA*, 922 F.3d 446 (D.C. Cir. 2019), granting in part and denying in part a petition for review of the 2017 Active-Inactive Rule (Ref. 5). The court decision impacted the CBI substantiation provisions set forth in 40 CFR 710.37 as discussed in more detail in the supplemental proposed rule (Ref. 6).

B. What did EPA propose?

On April 23, 2019, EPA proposed to establish a plan to review all CBI claims for specific chemical identities asserted in an NOA Form A, including the procedures for submitter substantiation and EPA review of those claims (Ref. 7).

In response to the court decision of April 26, 2019, EPA issued a supplemental proposed rule on November 8, 2019 that included revisions to the existing substantiation requirements in the 2017 Active-Inactive Rule at 40 CFR 710.37 and supplemented the proposed rule issued in April 2019. Specifically, EPA proposed two additional questions addressing a specific chemical identity's susceptibility to reverse engineering that manufacturers and processors would be required to answer to substantiate CBI claims for specific chemical identities asserted in an NOA Form A or B; and proposed procedures for manufacturers and processors to use in supplementing substantiations that had already been submitted under the 2017 Active-Inactive Rule to include responses to the two additional questions.

C. Public Comments

EPA received seven comments during the public comment period for the proposed rule, and an additional five comments during the comment period for the supplemental proposed rule. Submitted comments generally focused on the Agency's proposed substantiation and review processes as well as the duration of protection of CBI from disclosure. A number of commenters

requested clarification or provided suggestions that EPA considered in preparing this final rule. EPA has summarized the comments and provided detailed responses in a Response to Comments document that is available in the docket (Ref. 8).

III. Final Rule

After careful consideration of the public comments received, EPA is finalizing the substantiation requirements and the Agency's review plan as discussed in this unit.

A. CBI Claims for Specific Chemical Identities Asserted in NOAs Form A

1. Substantiation requirements.

a. Scope. This final rule establishes the substantiation requirements for manufacturers and processors who previously filed NOAs Form A seeking to maintain existing CBI claims to protect the specific chemical identities of active chemical substances on the confidential portion of the TSCA Inventory.

b. Persons subject to substantiation requirements. This final rule provides that any person who filed an NOA Form A requesting to maintain an existing CBI claim for a specific chemical identity must substantiate that confidentiality claim by addressing the substantiation questions in this rule, unless the person is eligible for an exemption. There are two exemptions in this rule which set forth reduced requirements for certain persons who have previously substantiated their CBI claims. These exemptions are substantively unchanged from the supplemental proposed rule.

The first exemption applies to those persons who previously completed the voluntary substantiation process set forth in the 2017 Active-Inactive Rule at 40 CFR 710.37(a)(1). These persons may rely on their previously submitted substantiation in lieu of answering the first six substantiation questions in this rule, and are only required to submit answers to the two questions

relevant to reverse engineering that are being finalized in 40 CFR 710.45(b)(7) and (8), signed and dated by an authorized official, and to complete the certification statement in 40 CFR 710.37(e).

The second exemption applies to those persons who previously substantiated their CBI claims for specific chemical identities in different submissions made to EPA less than five years before the substantiation deadline set forth in this rule. So long as that prior substantiation contains information that is responsive to all substantiation questions set forth in this rule at 40 CFR 710.45, these persons may rely on their prior substantiation in lieu of answering the substantiation questions in this rule. To establish eligibility for this exemption and to ensure that EPA can locate and match the prior substantiation with the proper NOA Form A filer, persons who seek to rely on this exemption must report 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 this rule. For example, substantiations for CBI claims for specific chemical identities submitted with 2016 or 2020 Chemical Data Reporting (CDR) submissions in accordance with the substantiation procedures at 40 CFR 711.30(b)(1), or with Notices of Commencement (NOCs) in accordance with the substantiation procedures at 40 CFR 720.85(b)(3)(iv), serve as a basis for this exemption.

A person who is eligible for an exemption may choose whether to take advantage of the reduced reporting under this rule afforded by the exemption or submit a new full substantiation in accordance with all requirements of this rule. Persons who have previously submitted a substantiation may prefer to complete a new substantiation under this rule if, for example, they wish to provide updated or additional information to support their CBI claim for a specific chemical identity.

c. Contents of substantiation. The final rule provides that a person substantiating a CBI claim for a specific chemical identity must submit written answers to the questions set forth in the rule at 40 CFR 710.45, signed and dated by an authorized official, and complete a certification statement. If information submitted in response to the substantiation questions is itself claimed as CBI, the submitter must clearly indicate such by marking that information as CBI.

In response to public comments, EPA has revised several of the proposed substantiation questions to improve clarity and reduce any unnecessary burden. First, EPA has chosen not to finalize one proposed question that asked whether the information claimed as confidential is exempt from substantiation pursuant to TSCA section 14(c)(2). EPA agrees with several commenters who noted that the question was neither necessary nor appropriate because no TSCA section 14(c)(2) exemption would ever apply to the CBI claims for specific chemical identities at issue in this rule. Second, in response to comments, EPA has clarified several of the substantiation questions proposed. While these questions remain substantively the same as those proposed (which, with the exception of the two reverse engineering questions addressed in the supplemental proposal, were identical to the questions in the 2017 Active-Inactive Rule at 40 CFR 710.37(c)), they have been re-written for clarity and to more clearly solicit answers potentially more responsive to the substantive criteria the Agency employs in making CBI determinations. Relevant public comments and the resulting changes to the substantiation questions are discussed in greater detail in the Response to Comments document (Ref. 8).

Most notably, EPA divided into three sub-questions the proposed substantiation question asking whether the confidential information appears in any public documents. Though the question as originally worded was intended to capture information in patents and patent

applications, state, local, or Federal agency files, and any document required to be publicly disclosed under any other Federal law, EPA rewrote the question to make this more explicit. In addition, EPA clarified the proposed reverse engineering question asking whether the chemical substance can be identified by analysis of the product. The finalized question asks more directly whether the specific chemical identity can be readily discovered by analysis of the substance (e.g., product, effluent, or emission), in light of existing technologies and any associated costs, difficulties, or limitations. Finally, EPA clarified the proposed substantiation question pertaining to substantial competitive harm to make clearer that responses should include an explanation of how a competitor could use such information and the causal relationship between the disclosure and the harmful effects.

d. When to submit substantiation or information on previous substantiation. The final rule provides at 40 CFR 710.47 that manufacturers and processors seeking to maintain CBI claims for specific chemical identities asserted in an NOA Form A will have 180 days from the effective date of the rule to submit substantiations, including responses to the two new substantiation questions, or, in the case of one of the exemptions, information identifying a previously submitted substantiation. This deadline applies to all persons who asserted CBI claims for specific chemical identities in an NOA Form A, including (1) persons newly substantiating their claims; (2) persons who voluntarily substantiated under the 2017 Active-Inactive Rule and need only submit responses to two substantiation questions under this rule; and (3) persons who substantiated their claims in some other submission within the last five years and need only submit information identifying that prior substantiation. EPA is finalizing a 180-day deadline in response to several comments from industry groups expressing concerns about meeting the proposed 90-day deadline.

e. Failure to report. In the proposed rule, EPA addressed the situation where a person filed an NOA Form A and asserted a CBI claim for a specific chemical identity, but never, either as a voluntary submission or per this rule, provided a substantiation or notice of prior substantiation. EPA had proposed to treat the CBI claim for a specific chemical identity as deficient because no substantiation was provided or referenced and proposed that the Agency may release the specific chemical identity to the public without further notice to the NOA Form A submitter. In response to comments, the final rule provides that when a person who asserted a CBI claim for a specific chemical identity in an NOA Form A failed to timely submit a substantiation or notice of prior substantiation, the CBI claim will be denied, and the submitter will be provided notice and an opportunity to seek judicial review of the final confidentiality determination in accordance with TSCA section 14(g)(2) and 40 CFR 2.306(e).

f. Electronic filing. The final rule provides that information must be submitted electronically via CDX in accordance with the existing regulation at 40 CFR 710.39. Prior to submission, this information must be generated and completed using the e-NOA software module. This is unchanged from what was proposed.

g. Record-keeping requirements. The final rule provides that persons subject to this rule must retain records for a period of five years beginning on the last day of the submission period. This is unchanged from what was proposed.

2. EPA's review plan.

This final rule also addresses the CBI claim review process, the duration of protection from disclosure, TSCA Inventory updates, the posting of annual review goals and results, and the timeframe for completion of Agency reviews. These provisions are substantively unchanged from the proposal.

a. Review criteria and procedures. The final rule provides that CBI claims for specific chemical identities asserted in NOAs Form A will be reviewed and approved or denied in accordance with the criteria and procedures in TSCA section 14 and 40 CFR part 2, subpart B. The final rule differs from the proposal in that a TSCA section 14 reference is added to the regulatory text to make explicit that the Agency's review criteria and procedures will follow the statutory requirements of TSCA. To the extent that there is any conflict between TSCA section 14 and 40 CFR part 2, subpart B, the statutory provision controls.

b. Duration of protection from disclosure. The final rule provides that a specific chemical identity whose CBI claim was approved by EPA will generally 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. The main exceptions to this period of protection from disclosure are (1) that if prior to the expiration of the period, the claimant notifies EPA that the person is withdrawing the confidentiality claim, EPA will not protect the information from disclosure from that date forward; or (2) if EPA otherwise becomes aware that the information does not qualify for protection from disclosure, the Agency will take the actions described in TSCA section 14(g)(2) to notify the claimant of EPA's intent to disclose the information. The period of protection is also subject to the exceptions and extensions to protection from disclosure enumerated in TSCA section 14. This is unchanged from what was proposed.

c. Updating the TSCA Inventory. The final rule provides that EPA will periodically update the TSCA Inventory based on the results of the reviews of the confidentiality claims for a specific chemical identity. This is unchanged from what was proposed.

d. Posting annual goals and numbers of reviews completed. The final rule provides that at the beginning of each calendar year until all reviews are completed, EPA will publish an annual

goal for reviews and the number of reviews completed in the prior year on the Agency website. This activity will begin in 2021, because substantiations are not required to be submitted to EPA until late 2020. The setting of annual review goals will take into consideration the number of claims needing review, available resources, and the statutory target completion date for all reviews to be completed not later than February 19, 2024. The final rule reflects a minor modification from the proposal to clarify that the posting of annual goals and number of reviews completed will cease upon completion of all reviews.

e. *Extension.* The final rule provides, consistent with the statute, that in the event that EPA determines that the target completion date cannot be met based on the number of claims needing review and the available resources, then EPA will publish a notice in the **Federal Register** announcing an extension of the deadline to complete its review of all confidentiality claims. The extension may not be for more than two additional years. EPA will provide an explanation of the reasons for the extension in the **Federal Register**. This is unchanged from what was proposed.

B. CBI Claims for Specific Chemical Identities Asserted in NOAs Form B

This final rule amends existing substantiation requirements set forth in 40 CFR 710.37(a)(2) and (c)(2) for CBI claims for specific chemical identities asserted in an NOA Form B. These amendments add two substantiation questions relevant to a specific chemical identity's susceptibility to reverse engineering, which claimants will be required to answer when substantiating such CBI claims in the future. The amendments also require any person who has already submitted an NOA Form B and substantiation on that form before the effective date of this final rule to supplement that substantiation within 30 days of the effective date of the final rule by adding responses to the two new questions. All other existing regulatory provisions in 40

CFR 710.37 applicable to the assertion, substantiation, certification, and review of CBI claims remain unchanged.

IV. Economic Analysis

The estimated incremental impacts of this rulemaking are briefly summarized in this unit and the complete Economic Analysis is available in the docket (Ref. 4). The rule requirements involve an incremental reporting effort for respondents who asserted CBI claims for one or more specific chemical identities in NOAs Form A during the one-time reporting period in 40 CFR part 710, subpart B. The rule requirements also involve an incremental reporting effort for respondents who assert(ed) CBI claims for one or more specific chemical identities in NOAs Form B. These reporting efforts consist of activities that are the same as or similar to those in the 2017 Active-Inactive Rule.

Respondents who submitted an NOA Form A and would potentially be subject to an incremental reporting effort fall into three groups based on the information provided in their submission. The first group (Group (1)) consists of those respondents who voluntarily submitted upfront CBI substantiation as part of the NOA submission process. The second group (Group (2)) consists of those respondents who did not voluntarily submit upfront CBI substantiation, but will be able to use the exemption offered under this rule by referencing a previous substantiation, such as one submitted under the 2016 or 2020 Chemical Data Reporting (CDR) rule (40 CFR part 711) or with a Notice of Commencement. The third group (Group (3)) consists of the remaining respondents who did not voluntarily submit upfront CBI substantiation in their NOA Form A submissions and would be required to provide full substantiation under this rule.

In addition to the three NOA Form A reporting groups, respondents who assert(ed) CBI claims for one or more specific chemical identities in NOAs Form B are subject to an

incremental reporting effort. This includes respondents who will submit an NOA Form B as part of ongoing reporting, as well as a set of 54 companies who asserted CBI claims for one or more specific chemical identities in NOAs Form B that was submitted during a one-time transitional reporting period.

Under this rule, the 275 companies who asserted CBI claims for one or more specific chemical identities in NOAs Form A incur a one-time burden and cost. For Group (1), the average one-time burden and costs per company are estimated at approximately 7 hours and \$543, respectively (involving an average of 21 chemicals per company) for rule familiarization, providing answers for two substantiation questions relating to reverse engineering, and recordkeeping. For Group (2), the average one-time burden and costs per company are estimated at 5 hours and \$390, respectively (involving an average of four chemicals per company), for rule familiarization, identification of a previous substantiation, and recordkeeping. For Group (3), the average one-time burden and costs per company are estimated at 39 hours, and \$3,039, respectively (involving an average of 27 chemicals per company), for rule familiarization, full substantiation, and recordkeeping.

Respondents who have filed or will file an NOA Form B that asserts a CBI claim for a specific chemical identity would be required to provide answers for two additional substantiation questions relating to reverse engineering. For NOA Form B submissions occurring on an annual basis, the average incremental burden and costs per company are estimated at approximately 0.38 hours and \$29, respectively (involving an average of two chemicals per company). For the 265 NOA Form B submissions from a total of 54 companies that were received during a one-time transitional reporting period, the total one-time burden and cost across all companies are estimated at approximately 50 hours and \$3,903, respectively.

The burden and cost estimates associated with the rule include a one-time burden associated with NOA Form A submissions, as well as an ongoing burden and one-time burden associated with NOA Form B submissions. A total of 275 companies are subject to a one-time burden associated with substantiating CBI claims for specific chemical identities asserted in NOAs Form A, including: Group (1), consisting of 149 companies, Group (2), consisting of 23 companies, and Group (3), consisting of 103 companies. The ongoing burden associated with NOA Form B submissions is based on the expectation that each year one company will submit an NOA Form B that includes CBI claims for two specific chemical identities and, therefore, incur a burden associated with ongoing reporting. Additionally, the one-time burden and cost estimates associated with this rule take into account a set of 265 NOA Form B submissions from a total of 54 companies that were received during a one-time transitional reporting period.

The total burden and costs associated with this rule consist of a one-time burden and cost for regulated entities estimated at 5,259 hours and \$406,852 and an ongoing annual burden and cost estimated at approximately 0.38 hours and \$29 for each year of a ten-year period. The equivalent annualized costs are expected to be \$47,729 at a three percent discount rate and \$57,968 at a seven percent discount rate (Ref. 4).

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 technical person listed under **FOR FURTHER INFORMATION CONTACT**.

1. EPA. Notice of Activity Form A; Final, 2017.
2. EPA. TSCA Inventory Notification (Active-Inactive) Requirements; Final Rule. **Federal Register**, 82 FR 37520, August. 11, 2017 (FRL-9964-22).
3. EPA. Notice of Activity Form B; Final, 2017.
4. EPA. Economic Analysis for the Final Rule: Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (RIN 2070-AK21). February 4, 2020.
5. U.S. Court of Appeals for the District of Columbia Circuit entered a judgment in *Environmental Defense Fund v. EPA*, 922 F.3d 446 (D.C. Cir. 2019).
6. EPA. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Revisions to the CBI Substantiation Requirements; Supplemental notice of proposed rulemaking. **Federal Register**, 84 FR 60363, November 8, 2019 (FRL-10001-44).
7. EPA. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory; Proposed Rule. **Federal Register**, 84 FR 16826, April 23, 2019 (FRL-9992-05).
8. 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.
9. EPA. Information Collection Request (ICR) Supporting Statement. Procedures for Review of CBI Claims for the Identity of Chemicals on the TSCA Inventory (Notice of Activity Form As). EPA ICR No.: 2594.03, OMB Control No.: 2070-0210. February 4, 2020.

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 not a significant regulatory action and was therefore not 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).

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

This action is not a regulatory action under Executive Order 13771 (82 FR 9339, February 3, 2017) because this action is not significant under Executive Order 12866.

C. Paperwork Reduction Act (PRA)

The information collection activities in this action 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 Requests (ICR) are assigned EPA ICR number ICR No. 2594.03 and OMB Control No. 2070-0210 (Ref. 9). You can find a copy of the ICR in the docket and it is briefly summarized here.

The reporting requirements identified in this action will provide EPA with information necessary to evaluate confidentiality claims and determine whether the claims qualify for protection from disclosure. EPA will review each CBI claim for specific chemical identity and related 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 under TSCA section 8 and 40 CFR part 710.

Estimated total number of potential respondents: 329 companies (one time) and 1 company annually (ongoing).

Frequency of response: Once per chemical substance.

Estimated total burden: 5,259 hours (one time) and 0.38 hours annually (ongoing). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: \$ 406,852 (one time) and \$29 annually (ongoing), includes no

annualized capital investment or maintenance and operational 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's regulations in 40 CFR are listed in 40 CFR part 9 and are displayed on the related collection instrument or form. 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.

D. Regulatory Flexibility Act (RFA)

Pursuant to section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, I certify that this final rule 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. The estimated economic impacts on small entities are presented in the Economic Analysis, (Ref. 4), which is available in the docket and briefly summarized here.

As a conservative approach, this small entity analysis applies the highest unit cost to all small entities. When considering the highest estimated average cost per company, the rule is not anticipated to have cost impacts greater than 1% on any small entities. Details of this analysis are included in the accompanying Economic Analysis for this final rule (Ref. 4).

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. This 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.

VII. 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 in 40 CFR Part 710

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

Dated: February 19, 2020.

Andrew R. Wheeler,

Administrator.

Therefore, 40 CFR chapter I, subchapter R, is amended as follows:

PART 710--[AMENDED]

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

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

Subpart B—Commercial Activity Notification

2. Amend § 710.37 by adding paragraph (a)(2)(i) and reserved paragraph (a)(2)(ii) and revising paragraph (c)(2) to read as follows:

§ 710.37 Confidentiality claims.

(a) * * *

(2) * * *

(i) Persons who submitted the information described in paragraph (a)(2) of this section before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] must submit answers to the questions in paragraphs (c)(2)(ii) and (iii) of this section not later than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**].

(ii) [Reserved]

* * * * *

(c) * * *

(2) *Substantiation for confidentiality claims for specific chemical identity.* (i) 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.

(ii) Does this particular chemical substance leave the site of manufacture (including

import) or processing in any form, *e.g.*, as a product, effluent, or emission? If yes, please explain what measures have been taken, if any, 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, or emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

* * * * *

3. Add subpart C to read as follows:

Subpart C—Review Plan

Sec.

710.41 Scope.

710.43 Persons subject to substantiation requirement.

710.45 Contents of substantiation.

710.47 When to submit substantiation or information on previous substantiation.

710.49 Failure to report.

710.51 Electronic filing.

710.53 Recordkeeping requirements.

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

§ 710.41 Scope.

This subpart 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) *Who must substantiate.* 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 in paragraph (b) of this section.

(b) *Exemptions.* (1) Any person who completed the voluntary substantiation process set

forth in § 710.37(a)(1) is exempt from the substantiation requirement of this subpart pertaining to the submission of answers to the questions in § 710.45(b)(1) through (6). All remaining requirements of § 710.45 must be met in accordance with the deadline specified in § 710.47(a), including the requirement to submit answers to the questions in § 710.45(b)(7) and (8), signed and dated by an authorized official, and to complete the certification statement in § 710.37(e).

(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, by submitting information that is responsive to all questions in § 710.45, 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 November 1, 2015; 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) *The submission.* A person substantiating a confidentiality claim for a specific chemical identity must submit written answers to the questions in paragraph (b) of this section, 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 paragraph (b) of this section is itself claimed as confidential, the submitter must clearly indicate such by marking that information as confidential business information.

(b) *Substantiation questions.* (1) 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.

(2) To the extent your business has disclosed the information to others (both internally and externally), 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.

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

(ii) 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.

(iii) Does any of the information claimed as confidential appear in one or more patents or patent applications? If yes, please provide the associated patent number or patent application number (or numbers) and explain why the information should be treated as confidential.

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

(5) 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 the information was found to be entitled to confidential treatment, the entity that made the decision, and the date of the determination.

(6) Is the confidential chemical substance publicly known (including by your competitors) to have ever been offered for commercial distribution in the United States? 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).

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

(8) 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, or emission), in light of existing technologies and any costs, difficulties, or limitations associated with such technologies? Please explain why or why not.

§ 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) or (b)(1) must submit their substantiation not later than November 1, 2020.

(b) All persons who seek an exemption under § 710.43(b)(2) must submit the information specified in § 710.43(b)(2)(ii) not later than November 1, 2020.

§ 710.49 Failure to report.

If neither the substantiation required under § 710.43(a) or (b)(1), nor the information

specified in § 710.43(b)(2)(ii), is submitted to EPA in accordance with the provisions of this subpart, then EPA will deny the confidentiality claim in accordance with the procedures set forth in TSCA section 14(g)(2) and 40 CFR part 2, subpart B.

§ 710.51 Electronic filing.

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

§ 710.53 Recordkeeping 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 TSCA section 14 and 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 until all reviews are completed, 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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