PRE-PUBLICATION NOTICE

On January 5, 2021, **Andrew R. Wheeler**, the EPA Administrator, signed the following document:

Action: Final Rule
Title: TSCA Inventory Notification (Active-Inactive); Reopening of the Reporting Period
FRL #: 10018-84
Docket ID #: EPA-HQ-OPPT-2016-0426

EPA is submitting this document for publication in the *Federal Register* (FR). EPA is providing this document solely for the convenience of interested parties. It is not the official version of the document for purposes of public notice and comment under the Administrative Procedure Act. This document is not disseminated for purposes of EPA's Information Quality Guidelines and does not represent an Agency determination or policy. While we have taken steps to ensure the accuracy of this Internet version of the document that was signed, the official version will publish in a forthcoming FR publication, which will appear on the Government Printing Office's govinfo website (https://www.govinfo.gov/app/collection/fr) and on Regulations.gov (https://www.regulations.gov) in the docket identified above.

Once the official version of this document is published in the *Federal Register*, this version will be removed from the Internet and replaced with a link to the official version. At that time, you will also be able to access the on-line docket for this *Federal Register* document at http://www.regulations.gov.

For further information about the docket and, if applicable, instructions for commenting, please consult the ADDRESSES section in the front of the Federal Register document.

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2016-0426; FRL-10018-84]

RIN 2070-AK24

TSCA Inventory Notification (Active-Inactive); Reopening of the Reporting Period

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The Environmental Protection Agency (EPA) is reopening the reporting period for retrospective active notifications for the Toxic Substances Control Act Chemical Substance Inventory (TSCA Inventory). This reopening is intended to provide an opportunity for companies to submit, amend, or withdraw the Notice of Activity Form A "active" notifications required for chemical substances on the TSCA Inventory that were manufactured (including imported) or processed for nonexempt commercial purposes during the 10-year time period ending on June 21, 2016, in order to make corrections to confidentiality claims and substantiations. EPA is reopening the reporting period because the Agency has become aware of submitter confusion and issues regarding confidential business information (CBI) claims during the initial reporting period. These issues may have inadvertently undermined existing, potentially valid, CBI claims for chemical identity. This rule neither approves any asserted CBI claim, nor abrogates the Agency's obligations to review the claim consistent with TSCA requirements.

DATES: This final rule is effective [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***].

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-

HQ-OPPT-2016-0426, 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*.

Due to the public health emergency, the EPA Docket Center (EPA/DC) and Reading Room is closed to visitors with limited exceptions. The staff continues to provide remote customer service via email, phone, and webform. For the latest status information on EPA/DC services and docket access, visit *https://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Scott M. Sherlock, Project Management and Operations Division (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. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you manufacture (including import)

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chemical substances listed on the TSCA Inventory. The following list of North American Industrial Classification System (NAICS) codes is not intended to be exhaustive, but rather provides a guide to help readers determine whether this document applies to them. Potentially affected entities may include but are not limited to:

- 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.**

B. What action is the Agency taking?

As amended in 2016, TSCA section 8(b) requires EPA to designate chemical substances on the TSCA Inventory as either "active" or "inactive" in U.S. commerce. To accomplish that, EPA finalized the TSCA Inventory Notification (Active-Inactive) Requirements Rule (Active-Inactive Rule) requiring industry reporting via a Notice of Activity Form A of chemicals manufactured (including imported) and providing for industry reporting of chemicals processed in the U.S. over a 10-year period ending on June 21, 2016 (82 FR 37520, August 11, 2017) (FRL-9964-22). This retrospective reporting was completed on October 5, 2018 and was used to identify chemical substances on the TSCA Inventory as active in U.S. commerce.

The Agency published a list of substances manufactured or processed for a non-exempt commercial purpose during the 10-year period ending on the day before the date of enactment of

the Frank R. Lautenberg Chemical Safety for the 21st Century Act which was June 21, 2016. If a chemical was on this list, the entity was exempted from filing a Notice of Activity Form A for the retrospective reporting requirement. However, if the chemical was treated as CBI, the chemical would lose its CBI status unless an entity filed a Notice of Activity Form A and asserted a CBI claim for the chemical identity. On March 6, 2020 (85 FR 13062; FRL-10005-48) EPA finalized CBI substantiation requirements, including filing deadlines, for entities that had made submissions via a Notice of Activity Form A claiming the chemical substance identities as CBI.

EPA is reopening the reporting period for retrospective notifications regarding the TSCA Inventory to allow companies to remedy issues regarding maintenance of existing CBI claims. The reopening will begin on [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE **FEDERAL REGISTER**] and it will remain open for 60 calendar days. This reopening is intended to provide an opportunity for companies to submit, amend, or withdraw the Notice of Activity Form As to remedy errors made regarding CBI claims only. The reopening will also allow for entities to provide CBI substantiations as required by 40 CFR part 710, Subpart C.

C. Why is EPA taking this action?

EPA is reopening the reporting period because the Agency has become aware that some entities did not understand the regulatory requirements for maintaining an existing CBI claim and, therefore, failed to make timely filings, or made errors in their Notice of Activity Form As during the reporting period that undermined the existing CBI claims, which might otherwise be valid if subject to a review pursuant to Agency regulations. The purpose of the rule amendment is to enable companies to submit, amend, or withdraw Notice of Activity Form As that allow entities to maintain existing CBI claims for specific chemical identity. This rule neither approves

any asserted CBI claim, nor abrogates the Agency's obligations to review the claim consistent with TSCA requirements.

In May of 2020, the Agency published an interim list of substances by the accession number, on the confidential portion of the TSCA Inventory the Agency expected to list on the public portion of the TSCA Inventory, noting "[t]he agency anticipates denying CBI claims for any chemical on this list." Since posting the list, EPA has been contacted by several entities seeking relief from the consequences of failing to comply with the requirements of the Rule or issues with submissions. These companies noted confusion about the requirements of the Active-Inactive Rule, lack of company, supplier, and customer coordination in addressing the Active-Inactive Rule, and mistakes in CBI claims in Notices of Activity Form As. In all instances these entities expressed concern about a loss of CBI claims, which might have withstood normal statute-based CBI review scrutiny.

The Agency is implementing this rule because inaction may cause financial injury to certain entities in the regulated community. The Agency has been informed that affected businesses would lose the confidential treatment of chemical identities unless the Agency reopens the reporting period for the Active-Inactive Rule. Certain entities have indicated to EPA that they either misunderstood the reporting requirements and did not submit the filings pursuant to the requirements of the Active-Inactive Rule or made mistakes in their filings. Under TSCA, a specific chemical name identifies every known structural feature intended to be part of a chemical substance's specific chemical identity, and it may also reveal process information, e.g., information on the manufacturing or processing of the chemical substance. Thus, as discussed subsequently in this document, when the chemical identity is on the confidential portion of the TSCA Inventory, it represents significant and valuable intellectual property, an important

innovation by the entity or its partner. Publicly revealing this information could result in the loss of this intellectual property, which could substantially injure a company's competitive position.

One company noted that not being able to remedy a deficient CBI claim would potentially cause a substantial competitive harm to the company and could likely lead to its closure. This company noted that it was a small family business, that because of its innovations it had been able to compete in a niche, specialty chemical market successfully against much larger competitors. The key to its success, the company asserted, for more than a half a century, was the development and marketing of a single specialty chemical. This chemical had consistently been treated as CBI, and competitors had not been able to reverse engineer the substance. If the chemical identity information were disclosed, the company asserted, competitors could duplicate it and employing, what the company termed "predatory pricing," to take the company's market share for the product and likely drive it out of business.

Another company observed that it found the Active-Inactive Rule confusing and mistakenly believed that it was exempt from the requirement to maintain an existing CBI claim because it met the requirements of the chemical reporting exemption in the Active-Inactive Rule. The company only realized it made a mistake after EPA published the May 2020 list of substances the Agency expected to list on the public portion of the TSCA Inventory. This entity communicated with its trade association and others in the industry and indicated to EPA it believed that the misunderstanding was widespread. Notably this company was not asking for approval of its CBI claims for all of its chemicals potentially subject to the Active-Inactive Rule. Rather, this entity only sought an opportunity to assert a CBI claim for chemicals that it believed would withstand a CBI review under TSCA.

Another company, while acknowledging that it failed to file because of mis-

understanding the requirements of the rule, observed that the consequence of the chemical identity disclosure would be to “substantially and unfairly damage” its competitive position and “destroy the value of our many years of investments” in research and development. The company noted that the chemical identity was a unique piece of intellectual property, which could not be identified by reverse engineering processes from physical samples of its formulated products. The best evidence of this was that the company’s competitors were also customers for the product. Disclosure of the chemical identity in this instance would allow these competitors to decipher the chemistry, replicate the chemistry, produce their own version, and drop the company as a supplier.

A trade association reported instances where processors that are customers of the entities that manufactured the chemical substance submitted a Notice of Activity Form A to ensure the chemical was on the active inventory but did not claim the reported chemical as confidential, thereby undermining the intellectual property of the chemical manufacturers. While the Agency had expected a level of coordination between manufacturers and processors, the Agency learned that in some cases this did not happen. One of these companies, a processor to an entity that had developed a substance treated as CBI, observed that it had no grounds to assert a CBI claim (as it had not developed the substance), so it did not seek the protection. Later the company-supplier contacted the processor and asked if it would consider rescinding or altering the submission in order for the chemical identity to remain as confidential. The processor agreed to this, noting that it was, after all, the other entity’s technology.

In each of the instances described previously, the entities seeking relief are either American companies or have a significant U.S. chemical manufacturing or processing presence. The Agency believes that not providing this limited relief will result in predictable harm to these

entities that could cause financial harm to the entities.

D. Who should consider reporting during this period?

Any entity (1) who was subject to the Active-Inactive Rule, (2) who would have reported a chemical on the confidential portion of the Inventory (e.g., any chemical that could only have been reported by accession number), and (3) who misunderstood the reporting requirements and did not file a Notice of Activity Form A or (4) may have made a mistake in the filing, should consider whether to submit, amend, or withdraw a Notice of Activity Form A during this reporting window. This reporting period is only for chemical substances listed on the confidential portion of the inventory. Entities who reported, or could have reported, a chemical that is on the public portion of the TSCA Inventory and could only report the chemical by CASRN should not utilize this reporting window.

There are several entities that misunderstood or overlooked the need to submit a Notice of Activity Form A to maintain an existing CBI claim in the initial reporting period because of the exemption in the Active-Inactive Rule for reporting the active status of the chemical substance. The exemption from reporting the active status does not extend to the maintenance of a substance's chemical identity as confidential; therefore, if those entities wish to maintain their existing CBI claims for chemical identity they should consider reporting during this window. Additionally, in some cases in the initial reporting period, multiple companies made submissions for the same chemical substance with at least one company electing to not maintain the chemical identity as CBI. Companies in this situation should consider coordinating in order to maintain an existing CBI claim for the chemical identity. If there are multiple reporters of the same chemical substance, and several claim it as confidential, and one does not, the CBI claim for chemical identity will be denied.

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

The Active-Inactive Rule was issued under the authority of TSCA section 8(b), 15 U.S.C. 2607(b), as is this amendment. This amended final rule sets the reopened reporting period at 30 days after publication in the Federal Register, consistent with the statutory requirement. In addition, section 553(b)(B) of the Administrative Procedure Act (APA), 5 U.S.C. 553(b)(B), provides that, when an agency for good cause finds that public notice and comment procedures are impracticable, unnecessary, or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. The EPA has determined that there is good cause for making this rule final, extending the reporting period, without prior proposal and opportunity for comment because such notice and opportunity for comment is impracticable for the reasons explained in this section.

As discussed in the prior section, companies may lose potentially legitimate confidentiality claims and face significant financial hardship due to misunderstandings and issues during the submission period unless the reporting period is reopened. A remedy is required expeditiously because of the Agency's obligation to release these chemical identities under TSCA. Under TSCA section 8(b)(4)(B)(iv), the Agency must "move any active chemical substance for which no request was received to maintain an existing claim for protection against disclosure . . . to the nonconfidential portion of [the Inventory]." Moreover, under TSCA section 8(b)(7)(C), the Agency must "make available to the public the specific chemical identity of any active substance" for which a confidentiality claim was not asserted.

Due to these provisions in TSCA, the issues during the initial reporting period could render the CBI claims invalid if reviewed by the Agency under TSCA sections 8(b)(4)(D), 14(g) or (f), in response to information requests or court orders, or pursuant to other authorities. Unless

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the rule is amended immediately, the Agency could be required to release specific chemical identities for which there are potentially legitimate CBI claims, permanently causing those entities to lose confidentiality protection for highly sensitive, proprietary information. If the CBI status of the chemical identity is not resolved before that review period ends, the CBI claim for the chemical identity is barred from CBI status in other TSCA contexts. The 2020 Chemical Data Reporting (CDR) Rule reporting period is open and will end January 29, 2021: if a CBI claim cannot be asserted in the Active-Inactive Rule, a CBI claim for that chemical would be denied in the CDR submission. Therefore, notice and comment is impracticable because the Agency has a legal obligation to release this information, within statutorily defined timeframes, unless there is a valid CBI claim.

This rule is to provide all affected entities an opportunity to maintain an existing CBI claim by filing and substantiating CBI claims, not to avoid the impacts of failing to meet a regulatory standard. As explained earlier, numerous business entities are impacted by this reporting rule and may lose potentially legitimate confidentiality claims without the opportunity to address issues in the submission process. The Agency has previously found that in many cases the specific chemical identity is one of the most commercially sensitive pieces of information submitted to the Agency. 48 FR 21722, 21730 (May 13, 1983). The importance of the confidential chemical identities is also reflected, in the number of chemicals (over 18,000) that are published on the confidential portion of the TSCA Inventory. The Agency must consider the economic impact of any action the Agency takes, TSCA sec. 2(c), and the economic impact of moving these confidential chemical identities to the non-confidential portion of the Inventory would potentially be significant.

Notice and comment would be impracticable because TSCA section 8(b)(4)(E) requires

EPA to complete reviews of all confidentiality claims received in Notice of Activity Form As not later than 5 years after February 19, 2019, i.e., the date on which the Administrator compiled the initial list of active substances pursuant to TSCA section 8(b)(4)(A). Under the review plan (85 FR 13062), EPA has an obligation to publish an annual goal for CBI reviews at the beginning of each calendar year and must take into consideration the number of claims needing review and a target completion date (40 CFR 710.55(d)). Engaging in notice and comment rulemaking would likely extend the period in which the Agency would continue to receive Notices of Activity Form A with confidentiality claims, potentially jeopardizing compliance with the deadline for review and its ability to publish its CBI review goals by January 2021. As discussed previously, the Agency only recently became aware of the misunderstandings within the regulated community regarding the requirements of the rule, and therefore could not have addressed these issues any sooner in a manner that would have not jeopardized compliance with the CBI review deadline.

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

This action does not create new reporting obligations, but instead provides an extended window of time for companies to comply with reporting requirements that were established in the Active-Inactive Rule.

II. Reopened Reporting Period

This rule reopens the reporting period in 40 CFR 710.30(a) for submission, amendments, or withdrawals of Notice of Activity Form As and the deadline for submission of the accompanying substantiations. This amended final rule sets the reopened reporting period at 30 days after publication in the Federal Register, consistent with the statutory requirement. The reporting period then runs for 60 days after that date.

III. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.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 Regulation 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 OMB under the PRA, 44 U.S.C. 3501 *et seq*. The Information Collection Request (ICR) is assigned EPA ICR number ICR No. 2594.04 and OMB Control No. 2070-2010. You can find a copy of the ICR in the docket and it is briefly summarized in this unit.

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 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.

Respondents/affected entities: Entities potentially affected by paperwork requirements of this final rule include manufacturers (including importers), processors, and distributors of chemicals substances regulated under TSCA.

Respondent's obligation to respond: Voluntary.

Frequency of response: Once per chemical substance.

Estimated total number of potential respondents: 483 companies (one time)

Estimated total burden: 11,564 hours (maximum one time). Burden is defined at 5 CFR 1320.3(b).

Estimated total costs: $894,887 (2017$) (maximum 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.

D. Regulatory Flexibility Act (RFA)

This action is not subject to the RFA, 5 U.S.C. 601 *et seq*. The RFA applies only to rules subject to notice and comment rulemaking requirements under the APA, 5 U.S.C. 553, or any other statute. This rule is not subject to notice and comment requirements under the APA because the Agency has invoked the APA "good cause" exemption. See Unit I.C.

E. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate of $100 million or more as described in UMRA, 2 U.S.C. 1531-1538 *et seq*., and does not significantly or uniquely affect small governments. This final rule is not expected to result in expenditures by State, local, and Tribal governments, in the aggregate, or by the private sector, of $100 million or more (when adjusted annually for inflation) in any one year. Accordingly, this final rule is not subject to the

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requirements of sections 202, 203, or 205 of UMRA.

F. Executive Order 13132: Federalism

This action does not have federalism impacts as defined in Executive Order 13132 (64 FR 43255, August 10, 1999) because this action will not have substantial direct effects on States, on the relationship between the Federal Government and States, or on the distribution of power and responsibilities between the Federal Government and States.

G. Executive Order 13175: Consultation and Coordination with Indian Tribal Governments

This action does not have tribal implications as defined in Executive Order 13175 (65 FR 67249, November 9, 2000) because this action will not have substantial direct effects on tribal governments, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

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 environmental health or safety risks that the EPA has reason to believe may disproportionately affect children, per the definition of "covered regulatory action" in section 2–202 of the Executive Order. This action is not subject to Executive Order 13045 because it does not concern an environmental health risk or safety risk.

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

This action is not subject to Executive Order 13211 (66 FR 28355, May 22, 2001), because this action is not a significant regulatory action under Executive Order 12866.

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 is not subject to Executive Order 12898 (59 FR 7629, February 16, 1994) because it does not establish an environmental health or safety standard. This action is a procedural change and does not have any impact on human health or the environment.

L. Congressional Review Act (CRA)

This action is subject to the CRA, 5 U.S.C. 801 *et seq.* and EPA will submit a rule report to each House of the Congress and to the Comptroller General of the United States. This action is not a "major rule" as defined by 5 U.S.C. 804(2).

List of Subjects in 40 CFR Part 710

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

Dated: ________________________.

Andrew Wheeler,

Administrator.

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Therefore, for the reasons set forth in the preamble, 40 CFR chapter I 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 § 710.30 by adding paragraph (a)(4) to read as follows:

*   *   *   *   *

(4) *Reopening of submission period*. Notwithstanding the provisions of (a)(1) through (3), manufacturers and processors reporting by accession number under § 710.25(a) and (b) may submit or amend Notice of Activity Form As to maintain an existing confidentiality claim for specific chemical identity, or withdraw Notice of Activity Form As between [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***] and [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***].

Subpart C—Review Plan

3. Amend § 710.47 to read as follows:

(a) All persons required to substantiate a confidentiality claim pursuant to § 710.43(a) or (b)(1) must submit the substantiation not later than [INSERT DATE 90 DAYS AFTER DATE OF PUBLICATION IN THE ***FEDERAL REGISTER***].