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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2016-0426; FRL-9956-28]

RIN 2070-AK24

TSCA Inventory Notification (Active-Inactive) Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: The recent amendments to the Toxic Substances Control Act (TSCA) require EPA to designate chemical substances on the TSCA Chemical Substance Inventory as either “active” or “inactive” in U.S. commerce. To accomplish that, EPA is proposing to require a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for non-exempt commercial purposes during the ten-year time period ending on June 21, 2016. EPA would also accept such notices for chemical substances that were processed. EPA would use these notifications to distinguish active substances from inactive substances. EPA would include the active and inactive designations on the TSCA Inventory and as part of its regular publications of the Inventory. EPA is also proposing to establish procedures for forward-looking electronic notification of chemical substances on the TSCA Inventory that are designated as inactive, if and when the manufacturing or processing of such chemical substances for non-exempt commercial purposes is expected to resume. Upon receipt of a valid notice, EPA would change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. EPA is proposing the procedures regarding the manner in which such retrospective

and forward-looking activity notifications must be submitted, the details of the notification requirements, exemptions from such requirements, and procedures for handling claims of confidentiality.

DATES: Comments must be received on or before [*insert date 60 days after date of publication in the Federal Register*].

ADDRESSES: Submit your comments, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0426, by one of the following methods.

- *Federal eRulemaking Portal:* <http://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 <http://www.epa.gov/dockets/contacts.html>. Additional instructions on commenting or visiting the docket, along with more information about dockets generally, is available at <http://www.epa.gov/dockets>.

FOR FURTHER INFORMATION CONTACT:

For technical information contact: Myrta R. Christian, Chemistry, Economics, and Sustainable Strategies Division (Mailcode 7401M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC

20460-0001; telephone number: (202) 564-8498; email address: *christian.myrta@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 domestically manufactured, imported, or processed chemical substances listed on the TSCA Chemical Substance Inventory for nonexempt commercial purposes during the ten-year time period ending on June 21, 2016. You may also be affected by this action if you intend to domestically manufacture, import, or process chemical substances listed on the TSCA Chemical Substance Inventory in the future. The following list of 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).

In addition, the discussion in Unit III.A. describes in more detail which chemical substances would and would not be subject to reporting under this proposed action. You may also consult 40 CFR 710.3 and 710.4, as well as the proposed regulatory text in this document, for further information on the applicability of exemptions to this proposed rule. 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**.

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

EPA is proposing this rule under TSCA section 8(b), 15 U.S.C. 2607(b). As described in more detail in Unit II.A., TSCA was amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act, Public Law 114-182. The Government Paperwork Elimination Act (GPEA), 44 U.S.C. 3504, provides that, when practicable, Federal organizations use electronic forms, electronic filings, and electronic signatures to conduct official business with the public.

Note that TSCA's statutory definition of "manufacture" includes importing. Accordingly, the regulatory definition of "manufacture" for this rule includes importation. All references to manufacturing in this notice 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 notice will do so expressly.

C. What action is the agency taking?

Pursuant to TSCA section 8(b)(4)(A), EPA is proposing procedural, retrospective notification requirements for persons who manufactured chemical substances on the TSCA Inventory as described in Unit III.A. Persons who manufactured these chemical substances for nonexempt commercial purposes during the ten-year time period ending on June 21, 2016, would be required to notify the Agency of certain information described in Unit III.C., including chemical identity and the date range when manufacture occurred in that ten-year time period. EPA would use the chemical identity information obtained from this retrospective reporting to designate as active those chemical substances on the TSCA Inventory for which notices were received. If no notice is received during this retrospective reporting for a chemical substance subject to designation on the TSCA Inventory, then that

substance would be designated as inactive. EPA would require date range information in order to obtain confirmation that the chemical substance in question had indeed been manufactured or processed between June 21, 2006 and June 21, 2016.

Pursuant to TSCA section 8(b)(5)(B), EPA is also proposing procedural, forward-looking notification requirements for persons who intend to manufacture or process inactive chemical substances on the TSCA Inventory. After EPA's first publication of the TSCA Inventory that includes active and inactive designations determined by the retrospective reporting, persons who intend to manufacture or process for nonexempt commercial purposes those chemical substances designated as inactive on the TSCA Inventory would be required to notify the Agency of certain information described in Unit III.C. Such notification must occur before the actual date of manufacturing or processing. EPA is proposing that notification, which shall include chemical identity and the actual date of manufacturing or processing, occur no more than 30 days before the actual date of manufacturing or processing.

Included in this proposed rule are electronic reporting requirements described in Unit III.D. that are similar to those established in 2013 for reporting other kinds of information to EPA under TSCA sections 4, 5, 8(a), and 8(d). See 78 FR 72818, December 4, 2013 (FRL 9394-6). The Agency is proposing to require submitters to use EPA's Central Data Exchange (CDX), the Agency's electronic reporting portal, for reporting information under this proposed rule. The information would be submitted to the Agency under TSCA section 8(b), but the practical rationales for requiring submissions to proceed through CDX, cited in 2013, are also pertinent here by analogy.

Also included in this proposal are amendments to 40 CFR part 710, which conform

the definitions applicable to these reporting requirements with those that apply to Chemical Data Reporting rule requirements (definitions found at 40 CFR 704.3 and 711.3) and the submission of Premanufacture Notifications (definitions found at 40 CFR 720.3). EPA believes that basing Section 8(b) reporting on definitions that are already familiar to the public from CDR and PMN reporting would reduce the potential for confusion and reduce the burden of rule familiarization. EPA is not proposing to modify the 40 CFR part 710 definitions in any manner that either is not conforming to Part 704, 710, or 720, or is a purely technical correction (e.g., eliminating references to the Canal Zone from the definition of “State”). Any other changes to the definitions in 40 CFR part 710 are beyond the scope of this proposal.

Included in this proposed rule are procedures for persons who co-manufacture or co-process a reportable chemical substance. These procedures would allow the submission of a single commercial activity notification in single instances of co-manufacturing or co-processing of a particular volume of a chemical substance. These proposed procedures are similar to Chemical Data Reporting rule requirements (40 CFR 711.22) when two or more persons are involved in a particular manufacture or import transaction. EPA believes that allowing a single notification for co-manufacturers and co-processors would serve to provide the Agency with the information necessary to designate a chemical substance as active on the TSCA Inventory while reducing duplicative reporting.

Also included in this proposed rule are requirements for filing a joint submission when specific chemical identity information is claimed confidential by a supplier. If an importer cannot provide the specific chemical identity of a reportable substance to EPA because the information is claimed confidential by a supplier, and therefore is unknown to

the importer, the importer would be required to ask the supplier to provide the confidential chemical identity information directly to the Agency in a joint submission. If a domestic manufacturer or processor cannot provide the specific chemical identity of a reportable substance to EPA because the chemical identity of a reactant is claimed confidential by a supplier, and therefore is unknown to the domestic manufacturer or processor, the manufacturer or processor would be required to ask the supplier to provide the confidential chemical identity information directly to the Agency in a joint submission. EPA would only accept joint submissions that are submitted electronically using CDX. This requirement is similar to Chemical Data Reporting rule requirements (40 CFR 711.15) and would allow EPA to obtain the information necessary to identify the specific chemical identity of a reportable substance and designate it as active on the TSCA Inventory.

D. Why is the agency taking this action?

TSCA section 8(b)(4)(A) requires EPA to issue a final retrospective reporting rule by June 22, 2017. These proposed reporting requirements would enable EPA to fulfill a statutory obligation to designate chemical substances on the TSCA Inventory as active or inactive in U.S. commerce. This proposed rule is not intended to indicate conclusions about the risks of chemical substances on the TSCA Inventory. Nonetheless, the designation of a chemical substance as active or inactive would be relevant to the Agency's prioritization of chemical substances in U.S. commerce under TSCA section 6(b).

Furthermore, TSCA section 8(b)(5) establishes a forward-looking notification requirement that goes into effect as soon as EPA designates inactive substances. EPA is proposing to establish the procedural framework whereby manufacturers and processors would discharge their notice obligations under this section of TSCA.

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. This analysis, which is available in the docket, is discussed in Unit VI. and is briefly summarized here (Ref. 1).

During the retrospective (or “start-up”) period, between approximately June 2017 and June 2018, typical costs per firm are estimated at \$1,346 per submission (with an estimated seven chemicals per submission), with possible additional costs at \$40.22 per CDX registration in the event that the submitter is not currently registered in CDX. Among manufacturers, an estimated 6,169 firms would undertake rule familiarization with 4,692 completing compliance determination, form completion, and recordkeeping. For manufacturers, the total burden during start-up is estimated at 86,783 hours with an associated total cost of \$6.68 million. For processors, the estimate of the universe of potentially affected firms is 161,550 who might initiate rule familiarization. For processors initiating rule familiarization, the cost would be 4 hours per firm (about \$300 per firm). EPA believes that it is unlikely that 100% of processors will initiate rule familiarization and that the percentage will be less. EPA estimates that only 100 processors will complete compliance determination, form completion, and recordkeeping. For the 100 processors who complete a submission with one chemical, the burden during start-up is estimated at 692 hours with an associated cost of \$0.05 million. Lastly, for 469 new CDX registrations (for individuals lacking previous experience with electronic reporting to EPA), burden during start-up is estimated at 249 hours with an associated cost of \$0.02 million.

The rule has minimal burden and cost implications related to ongoing reporting after the start-up year. The forward-looking (or “Ongoing”) reporting after June 2018 involves

compliance determination, form completion, and recordkeeping for twenty manufacturers and/or processors per year. Burden and cost are estimated to total 142 burden hours per year with an associated cost of \$10,790 per year.

Agency activities due to the rule include CDX and Chemical Information Submission System (CISS) capacity expansions, time to manage commercial activity notices, and increased costs incurred when making revisions to the TSCA Inventory. Associated costs are estimated at \$3.84 million during start-up, and \$0.20 million annually thereafter.

Combining Industry and Agency cost estimates, and annualizing over a 10-year period, the total cost of the rule is estimated at \$7.22 million per year using a 3% discount rate, and at \$8.77 million per year using a 7% discount rate.

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 information 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 would not be disclosed except in accordance with procedures set forth in 40 CFR part 2.

2. Tips for preparing your comments. When preparing and submitting your comments, see the commenting tips at <http://www.epa.gov/dockets/comments.html>.

II. Background

A. Overview of Applicable Authority

EPA is required under TSCA section 8(b), 15 U.S.C. 2607(b), to compile and keep current a list of chemical substances manufactured or processed in the United States. In 1977, EPA promulgated a rule under TSCA section 8(a), 15 U.S.C. 2607(a), to provide the information necessary for EPA to compile a list of chemical substances that had been in commerce since January of 1975 (Ref. 2). This list is known as the TSCA Chemical Substance Inventory (or simply the “TSCA Inventory”). Since compiling the initial TSCA Inventory, EPA regularly adds new chemical substances that have completed new chemical review requirements pursuant to TSCA section 5(a), 15 U.S.C. 2604(a), and that have been manufactured or processed for nonexempt commercial purposes. EPA maintains the TSCA Inventory as the authoritative list of all the chemical substances reported to the Agency for inclusion on the TSCA Inventory.

1. Retrospective reporting under TSCA section 8(b)(4)(A). TSCA section 8(b)(4)(A) requires EPA to promulgate a rule that requires manufacturers to notify the Agency, by not later than 180 days after the date on which the final rule is published in the **Federal Register**, of each chemical substance on the TSCA Inventory that was manufactured for nonexempt commercial purpose during the 10-year period ending on June 21, 2016. If EPA receives a valid notice for a chemical substance on the TSCA Inventory, EPA must designate that chemical substance as an active substance. If EPA receives no valid notice for a chemical substance on the TSCA Inventory (and that is subject to designation), EPA must designate that chemical substance as an inactive substance.

2. Forward-looking reporting under TSCA section 8(b)(5)(B). TSCA section 8(b)(5)(B) requires persons who intend to manufacture or process chemical substances for nonexempt commercial purposes in the future that are designated on the TSCA Inventory as

inactive to notify EPA prior to the date that these chemicals are to be manufactured or processed. Upon receiving a valid notice, EPA must change the designation of the chemical substance from inactive to active.

3. *Processors.* TSCA section 8(b)(4)(A) indicates that the Administrator may require processors to report similarly to manufacturers under the rule. This proposed rule would not require processors to report during the retrospective reporting period. However, once EPA has designated a chemical substance as an inactive substance, the processing of that chemical substance for a non-exempt commercial purpose would be unlawful, unless the processor first submits a notice as required by TSCA section 8(b)(5)(B). Therefore, this proposed rule would allow processors to report during the retrospective reporting period, extended to not later than 360 days after the date on which the final rule is published in the Federal Register (which will be 180 days after EPA's publication of the first version of the TSCA Inventory with preliminary commercial activity designations). Processors could report any chemical substance that they had processed for a nonexempt commercial purpose during the 10-year period ending on June 21, 2016. The extended submission period for processors would allow processors time to evaluate whether they wish to voluntarily report chemical substances that have not been reported by manufacturers or importers and that are preliminarily designated as inactive on EPA's publication of the first version of the revised TSCA Inventory. (These designations would be merely preliminary so there would not yet be an obligation to report under TSCA Section 8(b)(5)(B).) If EPA receives no notice on a chemical substance that is subject to designation, EPA then must designate that preliminarily inactive substance as actually inactive. Hence, persons who processed a chemical substance between June 2006 and June 2016 may wish to report under TSCA section 8(b)(4)(A) in order to avoid a

subsequent obligation to curtail processing on the day that EPA designates the substance as inactive, under TSCA section 8(b)(5)(B). Processing could resume as soon as the notice under TSCA section 8(b)(5)(B) is submitted, but processors may nonetheless find it less disruptive to ensure that the chemical substance is earlier reported as active under TSCA section 8(b)(5)(A).

4. General provisions. General provisions for TSCA section 8(b) rules appear in 40 CFR part 710. These provisions include definitions that apply to reporting under this proposed rule and also describe the scope of the Inventory. For example, 40 CFR 710.1 describes requirements for EPA to compile and keep current the TSCA Inventory of chemical substances manufactured or processed for commercial purposes, including the periodic updates to the Inventory to include new chemical substances reported under TSCA section 5(a) and commercialized for nonexempt purposes. In addition, the definitions in TSCA section 3 apply to this rulemaking.

5. Electronic reporting under the Government Paperwork Elimination Act (GPEA). GPEA, 44 U.S.C. 3504, provides that, when practicable, Federal organizations should use electronic forms, electronic filings, and electronic signatures to conduct official business with the public. EPA's Cross-Media Electronic Reporting Regulation (CROMERR) (40 CFR part 3), provides that any requirement in title 40 of the CFR to submit a notice directly to the Agency can be satisfied with an electronic submission that meets certain conditions once the Agency published a document in the **Federal Register** announcing that EPA is prepared to receive certain documents in electronic form (Ref. 3). For more information about CROMERR, go to <http://www.epa.gov/cromerr>.

III. Summary of Proposed Rule

EPA is proposing reporting and procedural requirements for manufacturers and processors of chemical substances pursuant to TSCA section 8(b).

A. What chemical substances would be reportable under this rule?

1. Reportable chemical substances. As a general matter, the retrospective reporting requirement of this proposed rule would apply to chemical substances listed on the TSCA Inventory that were manufactured for a nonexempt commercial purposes during the 10-year period ending on June 21, 2016. This lookback period is set by statute. TSCA also establishes forward-looking reporting requirements, at section 8(b)(5)(B), with respect to chemical substances listed on the TSCA Inventory that EPA designates as inactive. The TSCA Inventory is available at <https://www.epa.gov/tsca-inventory>.

2. Exemptions from reporting. i. Statutory background. This proposed rule provides exemptions from reporting based on sections 8(b)(4) and (5) and the general objectives that EPA can infer from that text. Unlike the reporting that informed the initial compilation of the TSCA Inventory (which arose under TSCA section 8(a)), the reporting requirements described in this proposed rule arise directly under TSCA section 8(b). EPA must finalize the retrospective reporting requirements by June 22, 2017, and all mandatory reporting under TSCA section 8(b)(4) must be completed by not later than 180 days thereafter. TSCA section 8(b)(4) and 8(b)(5) reporting requirements apply to “each chemical substance,” found on the TSCA Inventory, subject to the provision that reporting obligations shall only be triggered by manufacturing or processing for a “nonexempt commercial purpose.” The retrospective reporting requirements under TSCA section 8(b)(4) are expressed as being “subject to the limitations” of TSCA section 8(a)(5)(A). TSCA section 8(a)(5)(A), in turn, specifies that “to the extent feasible,” EPA shall: (1) avoid requiring reporting that is “unnecessary or

duplicative;” (2) “minimize the cost of compliance” to small manufacturers and processors; and (3) apply reporting obligations to the persons likely to have information relevant for effective implementation.

Furthermore, as EPA interprets its statutory authority, the reporting is intended to support two key objectives. First, to enable EPA to determine which reportable chemical substances are active in U.S. commerce. EPA will accomplish this based on notices received. Reportable chemical substances for which no notices are received would be considered inactive in U.S. commerce. See TSCA section 8(b)(4)(A)(iii). Second, with respect to chemical substances identified as being active in commerce that are listed on the confidential portion of the TSCA Inventory, to require that persons manufacturing or processing such chemical substances request that existing claims for protection against disclosure of the specific chemical identity be maintained. See TSCA sections 8(b)(4)(B)(ii), 8(b)(4)(C), 8(b)(5).

ii. Excluded chemical substances. If a chemical substance is not listed on the TSCA Inventory, then by the terms of TSCA sections 8(b)(4) and (5), it is not subject to reporting under this proposed rule. For example, chemical substances that are manufactured under a TSCA section 5(h) exemption are not added to the TSCA Inventory. Accordingly, this proposed rule would not require that reporting occur with respect to such substances. This is reflected in the proposed definitions at 40 CFR 710.23, which are drafted in such a manner that if a chemical substance was not on the TSCA Inventory as of June 22, 2016, it would not be subject to reporting.

Naturally occurring chemical substances also are proposed to be excluded from reporting under this proposed rule, so long as the manufacturing and processing of such

substances meets the criteria set forth in 40 CFR 710.27(b). When EPA required manufacturers and processors to submit notices in support of the original compilation of the TSCA Inventory in 1977, EPA made clear that reporting on naturally occurring chemical substances would not be necessary, as these substances would automatically be included in the Inventory as a category: “Naturally Occurring Chemical Substances,” 42 FR 64578 (1977). EPA proposes to simply designate the whole category of Naturally Occurring Chemical Substances as active substances, by rule, without the need for reporting to differentiate among such substances.

Finally, this proposed rule would not require manufacturers to report chemical substances that are on both the non-confidential portion of the TSCA Inventory and the interim list of active substances described in TSCA section 8(b)(6). Such reporting would be unnecessary, since EPA already has reporting data to establish that the chemical substance was in active commerce at some time between June 21, 2006 and June 21, 2016. Furthermore, for such substances, there are no existing claims for protection against disclosure of the specific identity of the chemical substance for any party to elect to maintain or not maintain. With respect to chemical substances on the confidential portion of the TSCA Inventory, however, such reporting still serves a statutory function under TSCA sections 8(b)(4)(B)(ii) and 8(b)(4)(C), even where there is already adequate evidence, prior to reporting, that the substance was in active commerce during the lookback period.

Regarding the composition of the interim list of active substances, TSCA section 8(b)(6) requires EPA to compile an interim list of active substances reported under 40 CFR part 711 for the purposes of TSCA section 6(b), before promulgation of the rule. The definition of the interim list is somewhat ambiguous, since it refers to the “reporting period

that most closely preceded June 22, 2016.” The term “reporting period” is not defined under 40 CFR part 711. In light of the definitional ambiguity of TSCA section 8(b)(6) and EPA’s weighing of the statutory objectives noted previously, EPA has construed the “interim list of active substances” to include 2012 CDR data, which avoids delay of this proposed rule, but would allow for the 2016 CDR data to give rise to a reporting exemption as soon as they are publicly released in final form. Under the proposal, manufacturers and processors of chemical substances on the non-confidential portion of the Inventory would be exempt from reporting if the manufacture of that chemical substance was already reported (by any party) in response to 2012 or 2016 CDR.

iii. Manufacturing or processing for an exempt commercial purpose. TSCA section 8(b) directs EPA to limit reporting obligations to manufacturing and processing for “nonexempt commercial purpose.” This phrase had a commonly-accepted usage at the time that TSCA was amended, in 2016. See, for example, “Certain New Chemicals; Receipt and Status Information” (referencing TSCA section 5 requirements as applying to manufacture for “nonexempt commercial purpose”) (Ref. 4), and “2016 Chemical Data Reporting Frequent Questions” (associating “nonexempt commercial purpose” with exemptions codified at 40 CFR 720.30 and 40 CFR 711.10(a)) (Ref. 5). Since reporting under TSCA section 8(b) is a form of existing chemical reporting, EPA construes the phrase “nonexempt commercial purpose” consistent with the manner in which the 40 CFR 720.30 exemptions from pre-manufacture reporting requirements were adapted for use in the CDR at 40 CFR 711.10. Thus, for example, the manufacturing or processing of chemical substances solely in small quantities for research and development would not trigger reporting obligations under this proposed rule. Similarly, the manufacturing or processing of impurities, or byproducts

that have no subsequent commercial purpose, would not trigger reporting obligations under this proposed rule. Finally, since the CDR integrates reporting exemptions for persons who import chemical substances solely as part of articles with reporting exemptions for nonexempt commercial purposes (see 40 CFR 711.10), EPA construes the TSCA 8(b) reference to “nonexempt commercial purpose” as also encompassing this article exemption. Further supporting this interpretation, EPA believes it would be incongruous to establish a more comprehensive reporting obligation for the import of inactive existing chemical substances under TSCA section 8(b)(5) (i.e., including import as part of an article), than would be applicable to the import of new chemical substances under TSCA section 5 (i.e., excluding import as part of an article).

3. *Chemical substances added to the Inventory on or after June 22, 2016.* In this proposed rule, chemical substances added to the Inventory on or after June 22, 2016 would be designated as active, without the need for any reporting to establish that the chemical substance is active and without the need for any statement by manufacturers or processors indicating whether such persons wish to maintain an existing claim for protection against disclosure of the specific chemical identity of the chemical substance. Reporting under TSCA section 8(b)(4) is based on manufacturing or processing, for non-exempt commercial purposes, that occurred between June 21, 2006 and June 21, 2016. TSCA section 8(b)(4)(A)(iii) directs EPA to classify a chemical substance as inactive if no notice of manufacturing or processing is received by EPA. A substance added to the Inventory on or after June 22, 2016, however, would be added so recently that it has no manufacturing or processing overlapping with the lookback period. It would be illogical to designate a very recent addition to the Inventory as inactive, on the grounds that the chemical substance was

too recently added to the Inventory to be captured in the retrospective reporting of current manufacturing and processing. Furthermore, if a chemical substance was added to the Inventory on or after June 22, 2016, then any claim for the protection against disclosure of the specific chemical identity of such a substance would be a new claim rather than the maintenance of an existing claim for protection of the information. For the reasons presented previously, EPA construes TSCA section 8(b)(4) reporting requirements to be limited to chemical substances that were added to the Inventory prior to June 22, 2016.

B. When would reporting be required?

1. Retrospective reporting period for manufacturers. This proposed rule would require manufacturers to report to the Agency not later than 180 days after the final rule is published in the **Federal Register**. The 180-day time period for this retrospective reporting for manufacturers is the maximum time allowed under TSCA section 8(b)(4)(A). Following this retrospective reporting for manufacturers, EPA would include the active and inactive designations, determined by the notices received, on the TSCA Inventory.

2. Retrospective reporting period for processors. This proposed rule would allow processors to report to the Agency not later than 360 days after the final rule is published in the **Federal Register**. The 360-day time period for this retrospective reporting for processors would allow processors to search EPA's publication of a first draft of the TSCA Inventory with active designations and draft inactive designations, based on retrospective reporting by manufacturers, and to report only those chemical substances not already reported. This first draft of the TSCA Inventory with active designations and draft inactive designations would not have the legal effect of actually designating any chemical substance as inactive. Processors would have the option to simply not report under TSCA section 8(b)(4) and

continue processing until such time when EPA has actually designated a chemical substance as inactive. At such time, any further processing of the chemical substance, without prior notification to EPA, would be prohibited by section 8(b)(5). Prior notification would allow EPA to add the chemical substance to the TSCA Inventory as an active substance.

3. Forward-looking reporting. After EPA completes its review of the notices submitted under TSCA section 8(b)(4)(A), it must designate as inactive any chemical substance (subject to designation) for which no notice was received. TSCA section 8(b)(5)(B) provides that, once a chemical substance has been designated as inactive, any person who intends to manufacture or process that inactive substance for a nonexempt commercial purpose must first notify the Agency before the date on which the inactive substance is manufactured or processed. EPA proposes to furthermore limit the submission period for such notices, so that they may not be submitted more than 30 days before the actual date of manufacturing or processing.

The 30-day time period for forward-looking reporting is based on EPA's experience with Premanufacture Notices (PMNs). Although persons often form the intent to commercially manufacture or process chemical substances several months ahead of time, EPA's experience with processing PMNs is that business decisions, technical difficulties, and other unforeseen circumstances may delay a company's plans to commercialize. EPA believes that a commercial activity notice reflects a more tentative or provisional intent to manufacture or process if it is submitted more than 30 days prior to the actual date of manufacturing or processing of the chemical substance. As such, it is less reliable as evidence that placement as active Inventory is warranted. Reassigning chemical substances from inactive to active status, based on relatively unreliable indicia of intent to manufacture,

could affect the reliability of the Inventory designations. Therefore, this proposed rule would require that forward-looking reporting of chemical substances designated as inactive on the TSCA Inventory occur not earlier than 30 days before companies intend to manufacturing or processing for nonexempt commercial purposes.

C. What information would be reported?

1. Retrospective reporting period for manufacturers. This proposed rule would require that manufacturers reporting for the retrospective reporting period provide certain information including chemical identity, type of commercial activity (i.e., whether it is domestic manufacture and/or import), date range of manufacture for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

2. Retrospective reporting period for processors. This proposed rule would allow processors to report for the retrospective reporting period, provided that the processor reports timely and consistent with the pertinent reporting requirements, including providing certain information such as chemical identity, date range of processing for nonexempt commercial purpose during the 10-year reporting period ending on June 21, 2016, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

3. Forward-looking reporting. TSCA section 8(b)(5) requires that manufacturers and processors of inactive substances notify EPA before the date on which they manufacture or process an inactive substance for non-exempt commercial purposes. This proposed rule stipulates that they would do so in the following manner: by reporting certain information

including chemical identity, type of commercial activity (i.e., whether it is domestic manufacture, import, and/or processing), actual date of manufacturing or processing for nonexempt commercial purpose, and whether they seek to maintain an existing claim for protection against disclosure of a confidential chemical identity, if applicable.

4. Reporting forms. EPA developed two versions of a Notice of Activity (NOA) reporting form for submitting the information described in this proposed rule for the two reporting scenarios, retrospective and forward-looking (Ref. 6). NOA Form A (EPA Form No. TBD-1) would be used by manufacturers for the retrospective reporting period. It would also be used by processors who report for the retrospective reporting period. NOA Form B (EPA Form No. TBD-2) would be used by manufacturers and processors for forward-looking reporting. The new NOA forms are based on EPA's Notice of Commencement (NOC) form (Ref. 7), since much of the information submitted in an NOC form is the same or similar to the information proposed in the NOA.

Any person required to report under this proposed rule would provide the information identified in the relevant version of the NOA forms to the extent it is known to or reasonably ascertainable by them. Drafts of the two versions of the proposed NOA reporting forms are available in the docket for public review (Ref. 6).

As noted previously, these forms require very basic explanatory information about the type of commercial activity at issue (domestic manufacture, import, or processing) as well as the date range over which the activity occurred or the date when the activity is intended to resume. The collection of this explanatory information is intended to reduce the likelihood of receiving erroneous notices (e.g., notices regarding commercial activity outside the lookback period), to support EPA's capacity to inquire into the accuracy of activity notices, and thus to

increase the reliability of commercial activity designations on the TSCA Inventory.

D. How would information be submitted to EPA?

In 2013, EPA finalized a rule to require electronic reporting of certain information submitted to the Agency under TSCA sections 4, 5, 8(a) and 8(d) (Ref. 8). The final rule followed two previous rules requiring similar electronic reporting of information submitted to the Agency for TSCA Chemical Data Reporting and Pre-Manufacture Notifications. This proposed rule would require electronic reporting similar to the requirements established in 2013 for submitting certain other information under TSCA (see 711.35 and 720.40). This proposed rule would require submitters to use EPA's CDX, the Agency's electronic reporting portal, and EPA's Chemical Information Submission System (CISS), a web-based reporting tool, for all reporting under this proposed rule in accordance with section 3.2000 of 40 CFR part 3 (CROMERR) (Ref. 3).

This proposed rule would require persons submitting notices of activity to EPA under TSCA section 8(b) to follow these same electronic reporting procedures used for other TSCA submissions, i.e., to register with EPA's CDX and use CISS to prepare a data file for submission. Registration in CDX enables CDX to authenticate identity and verify authorization. To register, the CDX registrant (also referred to as "Electronic Signature Holder" or "Public/Private Key Holder") agrees to the Terms and Conditions, provides information about the submitter and organization, and selects a user name and password. Users who have previously registered with CDX for other submissions would be able to add the "Submission for Chemical Safety and Pesticide Program" service to their current registration in CDX and use the CISS web-based reporting tool.

EPA developed the Chemical Information Submission System (CISS) for use in

submitting data electronically under TSCA sections 4, 5, 8(a), and 8(d) to the Agency. The tool is available for use with Windows, Macs, Linux, and UNIX based computers and uses “Extensible Markup Language” (XML) specifications for efficient data transmission across the Internet. CISS works with CDX to secure online communication and provides user-friendly navigation. The NOA forms described in this proposed rule will be included in an e-NOA software module in CISS. Once a user completes entry of the relevant data fields and metadata information in the appropriate NOA form, the CISS reporting tool validates the submission by performing a basic error check. CISS also allows the user to choose “Preview,” “Save,” or “Submit.” When “Submit” is selected, the user is asked to provide the user name and password that was created during the CDX registration process. CISS then submits the data via CDX. Upon successful receipt of the submission by EPA, the status of the submissions will be flagged as “Submitted.” The user can also login to the application and download their Copy of Record.

EPA believes that electronic reporting reduces the reporting burden for submitters by reducing the cost and time required to review, edit, and transmit data to the Agency. It also allows submitters to share a draft submission within their organization and more easily save a copy for their records or future use. The resource and time requirements to review, process, store, and retrieve data by the Agency would also be reduced.

Any person submitting a reporting form could claim any part or all of the form as confidential. Except as otherwise provided in this proposed rule, any information that is claimed as confidential would be disclosed by EPA only to the extent and by the means of the procedures set forth in 40 CFR part 2.

E. How would CBI claims and requests be handled?

Notices pursuant to this rulemaking may contain two different types of CBI assertions: claims for protection of information other than specific chemical identity, and requests to maintain existing claims for protection of specific chemical identity.

1. *Information other than specific chemical identity.* For all new claims for protection (i.e., for all CBI assertions under this rule other than requests to maintain existing claims for protection of specific chemical identity), TSCA section 14(c)(1)(B) and 14(c)(5) require that persons claiming CBI must provide a specific, certification statement regarding the basis for the CBI claims. In addition, this proposed rule would require that all such claims be substantiated at the time of submission, except for claims for information exempted from substantiation under section 14(c)(2). In view of the rapid EPA review of claims required by section 14(g)(1), and in order to reduce the likelihood of unwarranted claims, EPA believes that a concurrent substantiation is required. EPA will review a representative subset of these claims as specified by section 14(g)(1).

2. *Requests to maintain existing CBI claims for chemical identity.* Requests to maintain existing CBI claims for specific chemical identity on Form A are governed in part by TSCA sections 8(b)(4)(C-E). TSCA section 8(b)(4)(C), in particular, requires EPA to issue a rule to establish a review plan for these requests. That review plan must specify a time when the Form A CBI requests for specific chemical identity are to be substantiated. EPA will be conducting a separate rulemaking to establish this review plan. Therefore, this proposal does not include mandatory substantiation requirements for Form A CBI requests for chemical identity. Mandatory substantiation requirements will be part of the review plan promulgated under section 8(b)(4)(C). However, the Agency proposes to allow companies to submit early substantiation at the same time that their Form A is filed, if they so choose. As

long as the period between the date these earlier substantiations are received and the due date to be established in the review plan (yet to be proposed) is not more than five years, these early substantiations would exempt the company from the requirement to submit additional substantiation for their Form A under the terms of the review plan. See section 8(b)(4)(D)(i). EPA will review requests to maintain CBI claims for specific chemical identity in accordance with the 8(b)(4)(D) review plan in the timeframe mandated by section 8(b)(4)(E).

Any manufacturer or processor submitting an active chemical notification under TSCA section 8(b)(4)(A) may seek to maintain an existing CBI claim for specific chemical identity, regardless of whether that person asserted the original claim that caused the specific chemical identity to be treated as confidential. EPA believes this is the correct interpretation of “a manufacturer or processor . . . that seeks to maintain an existing claim for protection of against disclosure” of specific chemical identity. A number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, and the initial claimant may no longer exist. EPA does not believe that Congress intended for specific confidential chemical identities to be disclosed without providing the opportunity for manufacturers and processors to make a request that the identities should remain confidential simply because the original claimants no longer manufacture the chemical substances.

Pursuant to TSCA section 8(b)(4)(B)(iv), EPA would move an active chemical substance from the confidential portion of the Inventory to the non-confidential portion if no manufacturer or processor submitting an active chemical notification under TSCA section 8(b)(4)(A) requests to maintain the existing CBI claim for the specific identity of that chemical substance. See proposed 710.37(a).

Requests to maintain existing CBI claims for specific chemical identity on Form B

are governed by TSCA section 8(b)(5)(B), which provides that the request to maintain the claim must be substantiated not later than 30 days after submitting Form B. See section 8(b)(5)(B)(ii)(II). Proposed substantiation requirements for Form B CBI claims for chemical identity are found in section 710.37(a)(1)(ii).

Although TSCA section 8(b)(5) provides that substantiation for requests to maintain existing CBI claims for specific chemical identity must be provided not later than 30 days after submitting a Form B, persons submitting a Form B may find it more efficient to simply provide the substantiation for a CBI claim for specific chemical identity at the time of filing. Section 8(b)(5)(iii)(II) provides that the Agency shall “promptly” review CBI claims for specific chemical identity in Form B. The Agency intends to review these claims within 90 days of receipt of the substantiation.

IV. Request for Comments

EPA is seeking public comment on all aspects of this proposed rule, including specific issues throughout this document, as well as other issues discussed in this Unit.

A. Considerations for the agency’s Economic Impact Analysis.

EPA has evaluated the potential costs for manufacturers and processors of chemical substances reportable under this proposed rule (Ref. 1). EPA is specifically seeking additional information and data that the Agency could consider in developing the final economic analysis. In particular, EPA is seeking data that could facilitate the Agency’s further evaluation of the potentially affected industry and firms, including data related to potential impacts for those small businesses that would be subject to reporting.

B. Electronic Reporting.

Requiring electronic reporting under this proposed rule that is similar to those

established in 2013 for other TSCA reporting, EPA expects to save time, improve data quality, and provide efficiencies for both submitters and the Agency. EPA is specifically interested in comments related to the adoption of the existing mechanisms and procedures for use in transmitting the notices proposed in this rule, including comments related to the extent to which potential reporting entities are already familiar with these mechanisms and procedures because of their existing use for other TSCA reporting. EPA is also interested in feedback on how electronic reporting affects potential reporting entities in terms of reporting time, reporting efficiency, and potential burden associated with training to use the electronic systems (i.e., CDX and CISS).

V. References

The following is a listing of the documents that are specifically referenced in this proposed rule. The docket includes these references and other information considered by EPA. For assistance in locating these other documents, please consult the technical contact listed under **FOR FURTHER INFORMATION CONTACT**.

1. 2016. EPA. Burden and Cost Report for the Proposed Rule: TSCA Inventory Notification Requirements (RIN 2070-AK24, December 21, 2016).
2. 1977. EPA. Inventory Reporting Requirements; Final Rule. **Federal Register** (42 FR 64572, December 23, 1977) (FRL 817-1).
3. 2005. EPA. Cross-Media Electronic Reporting Rule (CROMERR); Final Rule. **Federal Register** (70 FR 59848, October 13, 2005) (FRL 7977-1).
4. 2010. EPA. Certain New Chemicals; Receipt and Status Information; Notice. **Federal Register** (75 FR 71688, November 24, 2010) (FRL 8852-1).
5. 2016. EPA. 2016 Chemical Data Reporting Frequent Questions.

<https://www.epa.gov/chemical-data-reporting/2016-chemical-data-reporting-frequent-questions>.

6. 2016. EPA. Notice of Activity Form A and Form B; Draft.
7. 2009. EPA. Notice of Commencement Form; Final.
8. 2013. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule. **Federal Register** (78 FR 72818, December 4, 2013) (FRL 9394–6).
9. 2016. EPA. Information Collection Request for the TSCA section 8(b) Proposed Reporting Requirements for TSCA Inventory Notification Active-Inactive (EPA ICR No. 2517.01).
10. 2016. EPA. Small Entity Analysis Report for the Proposed Rule: TSCA Inventory Notification Requirements (December 16, 2016).

VI. 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 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).

B. Paperwork Reduction Act (PRA)

The information collection activities associated with this proposed rule have been submitted to OMB for review and approval under the PRA, 44 U.S.C. 3501 *et seq.* Specifically, EPA has prepared an Information Collection Request (ICR) to estimate the

potential burden and costs associated with the proposed requirements (Ref. 9). The ICR, which is available in the docket, has been assigned the EPA ICR No. 2517.01 (OMB Control No. 2070-[new]). You can find a copy of the ICR in the docket for this proposed rule (Ref. 9), and it is briefly summarized here.

Start-Up Year Burden/Cost (Retrospective). Covers respondents/affected entities, i.e., persons who manufacture chemical substances.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents: 4,692.

Frequency of response: Once and on-occasion.

Estimated burden: 86,783 hours. The term "burden" is defined at 5 CFR 1320.3(b).

Estimated cost: \$6.68 million.

Note that an additional number of respondents (i.e., processors), as high as 161,550, are each assumed to undergo four hours of rule familiarization (about \$300 per firm), but would likely not be required to submit information. This is based on an assumption that 100 percent of processor firms would undertake rule familiarization. However, EPA believes that it is unlikely that 100% of processors would initiate rule familiarization and that the actual percentage would be lower. Although this count, and the associated burden and costs, are not included in the estimates, the estimated burden and costs account for the bulk of total start-up costs (88%). In addition, the estimated burden and costs includes 469 CDX registrations in addition to NOA submissions.

Ongoing Annual Burden/Cost (Forward-looking). Covers respondents/affected entities, i.e., persons who manufacture or process chemical substances.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents: 20.

Frequency of response: On-occasion.

Total estimated burden: 142 hours.

Total estimated cost: \$10,790.

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 EPA's regulations in 40 CFR are listed in 40 CFR part 9 and included on any related collection instrument (e.g., the form).

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 [*insert date 30 days after publication in the **Federal Register***]. EPA will respond to any ICR-related comments in the final rule.

C. Regulatory Flexibility Act (RFA)

EPA certifies under section 605(b) of the RFA, 5 U.S.C. 601 *et seq.*, that this action will not have a significant economic impact on a substantial number of small entities under the RFA. In making this determination, the impact of concern is any significant adverse economic impact on small entities. An agency may certify that a rule would not have a significant economic impact on a substantial number of small entities if the rule has a very small level of impact on the small entities subject to the rule.

The small entities subject to the requirements of this action are manufacturers, and processors of chemical substances. As the most burdensome conditions are incurred during the start-up year for manufacturers, these reporters are the subject of the quantitative analysis with other reporters and other years assessed by inference. The detailed analysis is available in the docket (Ref. 10).

The quantitative analysis addresses the “most affected” subset of entities who are expected to incur the highest typical burden under the proposed rule as entities manufacturing (or importing) chemicals that must submit NOAs involving an average of seven chemicals per entity in the start-up year. These small entities most directly regulated by this rule are small businesses in NAICS 325: Chemical Manufacturing, and 324: Petroleum and Coal Products Manufacturing reporting during the start-up year. EPA has determined that all of the small entities (comprising about 96% of the total number of entities) within the scope of the quantitative analysis would experience an impact of less than 1% of revenues. This analysis follows EPA guidance on Regulatory Flexibility Act (RFA) and Small Business Regulatory Enforcement Fairness Act (SBREFA) analyses. Per this guidance document, the preferred measure of economic impacts is the “sales test:” annualized compliance costs as a percentage of sales (or revenue or receipts when sales data are not readily available). This measure is termed “cost impact percentage” in the small entity analysis.

Additional groups of small entities may be affected by the rule and are expected to incur similar or lesser impacts, by inference. First, processors submitting NOAs during the start-up year are expected to incur a smaller unit burden with one chemical per NOA, and therefore experience similar or lesser impacts than manufacturers. Secondly, all reporters in

future years, with lower counts and relatively smaller unit burdens, would therefore incur much lower impact than entities during the start-up year. Therefore, inferences drawn regarding small entity impacts on the most affected group may be extended to characterize the impacts on processors during the start-up year and all entities for future years.

D. Unfunded Mandates Reform Act (UMRA)

This action does not contain an unfunded mandate as described in UMRA, 2 U.S.C. 1531–1538, and does not significantly or uniquely affect small governments. The action 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.

E. Executive Order 13132: Federalism

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

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

This action does not have tribal implications because it is not expected to have any effect 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, as specified in Executive Order 13175 (65 FR 67249, November 9, 2000).

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

Safety Risks

EPA interprets Executive Order 13045 (62 FR 19885, April 23, 1997), as applying only to those regulatory actions that concern 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.

H. 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.

I. 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.

J. 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 EPA has determined that this action would not have disproportionately high and adverse human health or environmental effects on minority or low-income populations. This action 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, Reporting and Recordkeeping, TSCA
Inventory.

Dated: December 23, 2016.

James J. Jones,

Assistant Administrator, Office of Chemical Safety and Pollution Prevention.

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

PART 710--[AMENDED]

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

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

2. Redesignate §§ 710.1 through 710.4 as subpart A under the following subpart A heading:

PART 710—COMPILATION OF THE TSCA CHEMICAL SUBSTANCE

INVENTORY

Subpart A—General Provisions

Sec.

710.1 Scope and compliance.

710.3 Definitions.

710.4 Scope of the Inventory.

Subpart B—Commercial Activity Notification

710.23 Definitions.

710.25 Persons subject to the notification requirement.

710.27 Activities for which notification is not required.

710.29 Information required in the notification.

710.30 When to submit notifications.

710.33 Co-manufacturers and co-processors.

710.35 Recordkeeping requirements.

710.37 Confidentiality claims.

710.39 Electronic filing.

* * * * *

5. Revise §710.1 paragraph (b) to read as follows:

Subpart A—General Provisions

§710.1 Scope and compliance.

* * * * *

(b) This part applies to the activities associated with the compilation of the TSCA Chemical Substance Inventory (TSCA Inventory) and the designation of chemical substances on the TSCA Inventory as active or inactive in U.S. commerce.

* * * * *

6. Revise § 710.3 paragraph (d) to read as follows:

§710.3 Definitions.

* * * * *

(d) The following definitions also apply to this part:

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

Administrator means the Administrator of the U.S. Environmental Protection Agency, any employee or authorized representative of the Agency to whom the Administrator may either herein or by order delegate his/her authority to carry out his/her functions, or any other person who will by operation of law be authorized to carry out such functions.

Article means a manufactured item (1) which is formed to a specific shape or design during manufacture, (2) which has end use function(s) dependent in whole or in part upon its shape or design during end use, and (3) which has either no change of chemical composition during its end use or only those changes of composition which have no commercial purpose separate from that of the article and that may occur as described in §710.4(d)(5); except that

fluids and particles are not considered articles regardless of shape or design.

Byproduct means a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance(s) or mixture(s).

CASRN means Chemical Abstracts Service Registry Number.

Chemical substance means any organic or inorganic substance of a particular molecular identity, including any combination of such substances occurring in whole or in part as a result of a chemical reaction or occurring in nature, and any chemical element or uncombined radical; except that “chemical substance” does *not* include: (1) any mixture; (2) any pesticide when manufactured, processed, or distributed in commerce for use as a pesticide; (3) tobacco or any tobacco product, but not including any derivative products; (4) any source material, special nuclear material, or byproduct material; (5) any pistol, firearm, revolver, shells, and cartridges; and (6) any food, food additive, drug, cosmetic, or device, when manufactured, processed, or distributed in commerce for use as a food, food additive, drug, cosmetic, or device.

Commerce means trade, traffic, transportation, or other commerce (1) between a place in a State and any place outside of such State or (2) which affects trade, traffic, transportation, or commerce between a place in a State and any place outside of such State.

Customs territory of the United States means the 50 States, Puerto Rico, and the District of Columbia.

Distribute in commerce and *distribution in commerce* means to sell in commerce, to introduce or deliver for introduction into commerce, or to hold after its introduction into commerce.

Domestic means within the geographical boundaries of the 50 United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, and any other territory or possession of the United States.

EPA means the U.S. Environmental Protection Agency.

Importer means any person who imports any chemical substance, including a chemical substance as part of a mixture or article, into the customs territory of the United States. "Importer" includes the person primarily liable for the payment of any duties on the merchandise or an authorized agent acting on his or her behalf. The term also includes, as appropriate, (1) the consignee, (2) the importer of record, (3) the actual owner if an actual owner's declaration and superseding bond has been filed in accordance with 19 CFR 141.20, or (4) the transferee, if the right to draw merchandise in a bonded warehouse has been transferred in accordance with subpart C of 19 CFR 144.

Impurity means a chemical substance which is unintentionally present with another chemical substance.

Intermediate means any chemical substance that is consumed, in whole or in part, in chemical reaction(s) used for the intentional manufacture of other chemical substance(s) or mixture(s), or that is intentionally present for the purpose of altering the rate(s) of such chemical reaction(s).

Inventory means the TSCA Chemical Substance Inventory, which is EPA's comprehensive list of confidential and non-confidential chemical substances manufactured or processed in the United States for non-exempt commercial purpose that EPA compiled and keeps current under section 8(b) of the Act.

Manufacture means to manufacture, produce, or import, for commercial purposes. Manufacture includes the extraction, for commercial purposes, of a component chemical substance from a previously existing chemical substance or complex combination of chemical substances. When a chemical substance, manufactured other than by import, is: (1) produced exclusively for another person who contracts for such production, and (2) that other person specifies the identity of the chemical substance and controls the total amount produced and the basic technology for the plant process, then that chemical substance is co-manufactured by the producing manufacturer and the person contracting for such production.

Manufacture for commercial purposes means: (1) to manufacture, produce, or import with the purpose of obtaining an immediate or eventual commercial advantage, and includes, among other things, the “manufacture” of any amount of a chemical substance or mixture (i) for commercial distribution, including for test marketing, or (ii) for use by the manufacturer, including use for product research and development or as an intermediate. (2) The term also applies to substances that are produced coincidentally during the manufacture, processing, use, or disposal of another substance or mixture, including byproducts that are separated from that other substance or mixture and impurities that remain in that substance or mixture. Byproducts and impurities without separate commercial value are nonetheless produced for the purpose of obtaining a commercial advantage, since they are part of the manufacture of a chemical substance for commercial purposes.

Manufacturer means a person who manufactures a chemical substance.

Mixture means any combination of two or more chemical substances if the combination does not occur in nature and is not, in whole or in part, the result of a chemical reaction; except that “mixture” does include (1) any combination which occurs, in whole or

in part, as a result of a chemical reaction if the combination could have been manufactured for commercial purposes without a chemical reaction at the time the chemical substances comprising the combination were combined, and if all of the chemical substances comprising the combination are not new chemical substances, and (2) hydrates of a chemical substance or hydrated ions formed by association of a chemical substance with water, so long as the nonhydrated form is itself not a new chemical substance.

New chemical substance means any chemical substance which is not included on the Inventory.

Person includes any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity; any State or political subdivision thereof; any municipality; any interstate body; and any department, agency, or instrumentality of the Federal Government.

Process means to process for commercial purposes. Process includes the preparation of a chemical substance or mixture, after its manufacture, (1) in the same form or physical state as, or in a different form or physical state from, that in which it was received by the person so preparing such substance or mixture, or (2) as part of a mixture or article containing the chemical substance or mixture.

Process for commercial purposes means the preparation of a chemical substance or mixture after its manufacture for distribution in commerce with the purpose of obtaining an immediate or eventual commercial advantage for the processor. Processing of any amount of a chemical substance or mixture is included in this definition. If a chemical substance or mixture containing impurities is processed for commercial purposes, then the impurities also are processed for commercial purposes.

Processor means any person who processes a chemical substance or mixture.

Site means a contiguous property unit. Property divided only by a public right-of-way will be considered one site. More than one manufacturing plant may be located on a single site. (1) For chemical substances manufactured under contract, i.e., by a toll manufacturer, the site is the location where the chemical substance is physically manufactured. (2) The site for an importer who imports a chemical substance described in §710.25 is the U.S. site of the operating unit within the person's organization that is directly responsible for importing the chemical substance. The import site, in some cases, may be the organization's headquarters in the United States. If there is no such operating unit or headquarters in the United States, the site address for the importer is the U.S. address of an agent acting on behalf of the importer who is authorized to accept service of process for the importer.

Small quantities solely for research and development (or "small quantities solely for purposes of scientific experimentation or analysis or chemical research on, or analysis of, such substance or another substance, including such research or analysis for the development of a product") means quantities of a chemical substance manufactured, imported, or processed or proposed to be manufactured, imported, or processed solely for research and development that are not greater than reasonably necessary for such purposes.

State means any State of the United States, the District of Columbia, the Commonwealth of Puerto Rico, the Virgin Islands, Guam, American Samoa, the Northern Mariana Islands, or any other territory or possession of the United States.

Technically qualified individual means a person (1) who because of his/her education, training, or experience, or a combination of these factors, is capable of appreciating the health and environmental risks associated with the chemical substance which is used under

his/her supervision, (2) who is responsible for enforcing appropriate methods of conducting scientific experimentation, analysis, or chemical research in order to minimize such risks, and (3) who is responsible for the safety assessments and clearances related to the procurement, storage, use, and disposal of the chemical substance as may be appropriate or required within the scope of conducting the research and development activity. The responsibilities in this paragraph may be delegated to another individual, or other individuals, as long as each meets the criteria in paragraph (1) of this definition.

Test marketing means the distribution in commerce of no more than a predetermined amount of a chemical substance, mixture, or article containing that chemical substance or mixture, by a manufacturer or processor to no more than a defined number of potential customers to explore market capability in a competitive situation during a predetermined testing period prior to the broader distribution of that chemical substance, mixture, or article in commerce.

United States, when used in the geographic sense, means all of the States, territories, and possessions of the United States.

7. Add a new subpart B to read as follows:

Subpart B—Commercial Activity Notification

§710.23 Definitions.

The following definitions also apply to subpart B of this part.

Active substance means any interim active substance, any naturally occurring chemical substance as defined by § 710.27(b), any substance added to the TSCA Inventory on or after June 22, 2016, and any chemical substance subject to commercial activity

designation that the Administrator designated as active based on the receipt of a notice under this subpart.

Central Data Exchange or CDX means EPA's centralized electronic document reporting portal, or its successors.

Chemical substance subject to commercial activity designation means a chemical substance that requires a designation as either an active or an inactive substance. A chemical substance is subject to commercial activity designation if it was added to the TSCA Inventory before June 22, 2016, it is not an interim active substance, it is not a naturally occurring chemical substance as defined by § 710.27(b), and it has not yet been designated by the Administrator as either an active or an inactive substance.

Chemical Information Submission System or CISS means EPA's web-based reporting tool for preparing and submitting a Notice of Activity.

e-NOA means EPA's software module within CISS for generating and completing Notice of Activity forms A and B.

Existing claim for protection of specific chemical identity against disclosure is a claim to continue protection of specific chemical identity of a chemical substance that is listed on the confidential portion of the TSCA Inventory.

Inactive substance means any chemical substance subject to commercial activity designation, that the Administrator designates as inactive based on the lack of receipt of a notice under this subpart.

Interim active substance means any chemical substance that was reported, pursuant to 40 CFR part 711, as having been manufactured in either 2010 or 2011. After such time when EPA has made public a compiled list of chemical substances that were reported, pursuant to

40 CFR part 711, as having been manufactured in either 2012, 2013, 2014, or 2015, the term shall also include any such additional chemical substances that were there reported as having been manufactured in those additional years.

Known to or reasonably ascertainable by means all information in a person's possession or control, plus all information that a reasonable person similarly situated might be expected to possess, control, or know.

Lookback period means the period beginning on June 21, 2006 and ending on June 21, 2016.

Reportable chemical substance means a chemical substance that is listed on the TSCA Inventory and that is either: (1) a chemical substance subject to commercial activity designation for which notification is required or allowed under § 710.25(a) and § 710.25(b), (2) an interim active substance for which notification is required under § 710.25(a), or (3) an inactive substance for which notification is required under § 710.25(c).

Submission period means the applicable period for submitting a Notice of Activity under § 710.25.

§710.25 Persons subject to the notification requirement.

The following persons are subject to the requirements of this subpart.

(a) *Who must submit the Notice of Activity Form A?* Any person who manufactured a chemical substance subject to commercial activity designation or who manufactured an interim active substance that is on the confidential portion of the TSCA Inventory, at any time during the lookback period, except as provided in §710.27, must submit a Notice of Activity Form A as specified under §710.29 and §710.30.

(b) *Who else may submit the Notice of Activity Form A?* Any person who processed a

chemical substance subject to commercial activity designation, at any time during the lookback period, except as provided in §710.27, may submit a Notice of Activity Form A as specified under §710.29 and §710.30.

(c) *Who must submit the Notice of Activity Form B?* Any person who intends to manufacture or process an inactive chemical substance, except as provided in §710.27, after the effective date of the Administrator's designation of such chemical substance as an inactive substance, must submit a Notice of Activity Form B as specified under § 710.29 and § 710.30.

§710.27 Activities for which notification is not required.

(a) *In general.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacturing or processing of a chemical substance solely in small quantities for research and development.

(2) The import of a chemical substance as part of an article.

(3) The manufacturing or processing of a chemical substance as described in § 720.30(g) or (h).

(b) *Manufacturing or processing naturally occurring chemical substances.* The following activities do not trigger notification requirements under this subpart:

(1) The manufacture of a naturally occurring chemical substance, as described in § 710.4(b). Some chemical substances can be manufactured both as described in § 710.4(b) and by means other than those described in § 710.4(b). If a person manufactures a chemical substance by means other than those described in § 710.4(b), this exemption is inapplicable, regardless of whether the chemical substance also could have been produced as described in

§ 710.4(b). This exemption does not cover the manufacture of a chemical substance from a naturally occurring chemical substance.

(2) The processing of a naturally occurring chemical substance only by manual, mechanical, or gravitational means; by dissolution in water; by flotation; or by heating solely to remove water.

§710.29 Information required in the notification.

(a) *Reporting information to EPA.* Any person who reports information to EPA, including post-notification substantiation of confidentiality claims under § 710.37(b), must do so using the e-NOA software module, the CISS reporting tool, and the CDX electronic reporting portal provided by EPA at the addresses set forth in §710.39. For notices of activity under § 710.25(a) and § 710.25(b), the submission must include all information described in paragraph (b) of this section. For a Notice of Activity under § 710.25(c), the submission must include all information described in paragraph (c) of this section. A person must submit a separate form for each chemical substance that the person is required to report. CDX, CISS, and e-NOA allow a person to report multiple chemical substances in one session that will be transmitted to EPA on separate forms. Using e-NOA and registering in CDX are described in instructions available from EPA at the websites set forth in §710.39.

(b) *Information to be reported on the Notice of Activity Form A.* Any person submitting a Notice of Activity Form A under § 710.25(a) or § 710.25(b) must submit the information described in this paragraph for each reportable chemical substance during the submission period specified in § 710.30(a). A person submitting information under § 710.25(a) or § 710.25(b) must report information to the extent that such information is known to or reasonably ascertainable by that person. A notice must be submitted for each

chemical substance for which the person is required to report. A person reporting information under § 710.25(a) or § 710.25(b) must report the following:

(1) Information specified in § 710.29(d).

(2) The type of commercial activity for each reportable chemical substance: whether the chemical substance was domestically manufactured in the United States, imported into the United States, or both domestically manufactured in the United States and imported into the United States during the lookback period.

(3) The first date and the last date that each reportable chemical substance was domestically manufactured in the United States, imported into the United States, or both domestically manufactured in the United States and imported into the United States during the lookback period.

(c) *Information to be reported on a Notice of Activity Form B.* Any person submitting a Notice of Activity Form B under § 710.25(c) must provide the information described in this paragraph for each inactive chemical substance intended to be manufactured or processed at the time specified in § 710.30(b). A person submitting information under § 710.25(c) must report information to the extent that such information is known to or reasonably ascertainable by that person. A notice must be submitted for each chemical substance that the person intends to manufacture or process. A person submitting a notice of activity under § 710.25(c) must report the following:

(1) Information specified in § 710.29(d).

(2) The type of intended commercial activity for the inactive substance: whether the inactive substance is intended to be domestically manufactured in the United States, imported into the United States, processed in the United States, or a particular combination of these.

(3) The actual date by which the inactive substance is to be domestically manufactured in the United States, imported into the United States, or processed in the United States.

(d) *Information to be reported on either the Notice of Activity Form A or Form B*

(1) *Company.* The name of the submitting company.

(2) *Authorized official.* The name and address of the authorized official for the submitting company.

(3) *Technical contact.* The name and telephone number of a person who will serve as technical contact for the submitting company and who will be able to answer questions about the information submitted by the company to EPA.

(4) *Chemical-specific information.* The correct CA Index name as used to list the chemical substance on the Inventory and the correct corresponding CASRN must be submitted for each reportable chemical substance. Persons who wish to report chemical substances listed on the confidential portion of the TSCA Inventory must report the chemical substances using a TSCA Accession Number and generic name.

(i) If an importer submitting a notice cannot provide the information specified in § 710.29(d)(4) because it is unknown to the importer and claimed as confidential by the supplier of the chemical substance or mixture, the importer must ask the supplier to provide the specific chemical identity information directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must include instructions for submitting chemical identity information electronically, using e-NOA, CISS, and CDX (see § 710.39), and for clearly referencing the importer's submission. Contact information for the supplier, a trade name or other name for the chemical substance

or mixture, and a copy of the request to the supplier must be included with the importer's submission with respect to the chemical substance.

(ii) If a manufacturer or processor submitting a notice cannot provide the information specified in § 710.29(d)(4) because the reportable chemical substance is manufactured or processed using a reactant having a specific chemical identity that is unknown to the manufacturer or processor and claimed as confidential by its supplier, the manufacturer or processor must ask the supplier of the confidential reactant to provide the specific chemical identity of the confidential reactant directly to EPA in a joint submission using the same e-NOA software module used for commercial activity reporting. Such request must include instructions for submitting chemical identity information electronically using e-NOA, CISS, and CDX (see § 710.39), and for clearly referencing the manufacturer's or processor's submission. Contact information for the supplier, a trade name or other name for the chemical substance, and a copy of the request to the supplier must be included with the manufacturer's or processor's submission with respect to the chemical substance.

(iii) EPA will only accept joint submissions that are submitted electronically using e-NOA, CISS, and CDX (see § 710.39) and that clearly reference the primary submission to which they refer.

(5) *Certification statement.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part and that the confidentiality claims made on the form are true and correct using the certification statement in this paragraph.

(i) The certification must be signed and dated by the authorized official for the submitting company.

(ii) The following is the required certification language:

“I certify under penalty of law that this document and all attachments were prepared under my direction or supervision and the information contained therein, to the best of my knowledge is, true, accurate, and complete. I am aware there are significant penalties for submitting incomplete, false and/or misleading information, including the possibility of fine and imprisonment for knowing violations.”

§710.30 When to submit notifications.

(a) *When must a Notice of Activity Form A be submitted?* The Notice of Activity Form A required to be submitted under § 710.25(a) must be submitted during the applicable submission period.

(1) *Manufacturers.* The submission period for manufacturers under § 710.25(a) begins on [date on which the final rule is published in the **Federal Register**] and ends on [180 days after the date on which the final rule is published in the **Federal Register**].

(2) *Processors.* The submission period for processors under § 710.25(b) begins on [date on which the final rule is published in the **Federal Register**] and ends on [360 days after the date on which the final rule is published in the *Federal Register*].

(b) *When must a Notice of Activity Form B be submitted?* The Notice of Activity Form B required to be submitted under § 710.25(c) must be submitted before a person manufactures or processes the inactive substance, but not more than 30 days prior to the actual date of manufacturing or processing.

§710.33 Co-manufacturers and co-processors.

(a) *Notice of Activity submitted by co-manufacturers.* When, in a single instance of manufacturing or importing a particular volume of a chemical substance during the lookback

period, two or more persons qualify as the manufacturer or importer of that volume, they may determine among themselves who should make the required submission under § 710.25(a). If no notice is submitted as required under this subpart, EPA will hold each such person liable for failure to submit a notice.

(b) *Notice of activity by prospective co-manufacturers or co-processors.* If two or more persons intend to manufacture, import, or process a particular volume of an inactive substance, such that multiple persons would qualify as the manufacturer, importer, or processor of that volume, they may determine among themselves who will submit the required notice under § 710.25(c). If no notice is submitted as required under this subpart, all of the persons remain subject to the reporting requirements, and EPA will hold each such person liable for a failure to submit a notice prior to the date of manufacturing, importing, or processing.

§710.35 Recordkeeping requirements.

Each person who is subject to the notification requirements of this part must retain records that document any information reported to EPA. Records relevant to a notice of activity under § 710.25(a) and § 710.25(b) must be retained for a period of 5 years beginning on the last day of the submission period. Records relevant to a notice of activity under § 710.25(c) must be retained for a period of 5 years beginning on the day that the notice was submitted.

§710.37 Confidentiality claims.

(a) *Chemical identity.* Any persons submitting information under this part may request to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance only if the identity of the chemical substance is listed on the

confidential portion of the TSCA Inventory as of the time the notice is submitted for that chemical substance under this part. Any such requests to maintain an existing claim of confidentiality must be made at the time the information is submitted. If no person submitting the information specified in § 710.29(d)(4) for a particular chemical substance requests that the claim be maintained, EPA will treat the specific chemical identity of that chemical substance as not subject to a confidentiality claim and will move the chemical substance to the public portion of the TSCA Inventory. Except as set forth in this subsection, information claimed as confidential in accordance with this section will be treated and disclosed in accordance with the procedures in 40 CFR part 2. The following steps must be taken to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance.

(1) *Substantiation of requests.*

(i) *Notice of Activity Form A.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity may submit with the notice detailed written answers to the questions in paragraph (1)(iii) of this section, signed and dated by an authorized official. If these early answers are received less than five years before the date on which substantiation is due pursuant to TSCA Section 8(b)(4)(D)(i) the early answers will be deemed to be substantiations made under TSCA Section (8)(b)(4)(D)(i) and the person will be exempt from further substantiation requirements under Section (8)(b)(4)(D)(i). Early answers that do not include the answers to questions in paragraph (1)(iii) of this section will not be deemed to be substantiations made under the TSCA section (8)(b)(4)(D)(i) requirement.

(ii) *Notice of Activity Form B.* A person requesting to maintain an existing claim of

confidentiality for specific chemical identity must submit detailed written answers to the questions in paragraph (1)(iii) of this section within 30 days of submitting the notice, signed and dated by an authorized official. If this information is not submitted within 30 days of submitting the notice, EPA will consider the specific chemical identity as not subject to a confidentiality claim and may make the information public without further notice.

(iii) *Substantiation questions.*

(A) What harmful effects to your competitive position, if any, or to your supplier's competitive position, do you think would result from the identity of the chemical substance being disclosed in connection with reporting under this part? How could a competitor use such information? Would the effects of disclosure be substantial? What is the causal relationship between the disclosure and the harmful effects?

(B) How long should confidential treatment be given? Until a specific date, the occurrence of a specific event, or permanently? Why?

(C) Has the chemical substance been patented? If so, have you granted licenses to others with respect to the patent as it applies to the chemical substance? If the chemical substance has been patented and therefore disclosed through the patent, why should it be treated as confidential?

(D) Has the identity of the chemical substance been kept confidential to the extent that your competitors do not know it is being manufactured for a commercial purpose by anyone?

(E) Is the fact that the chemical substance is being manufactured for a commercial purpose available to the public, for example in technical journals, libraries, or State, local, or Federal agency public files?

(F) What measures have been taken to prevent undesired disclosure of the fact that the chemical substance is being manufactured for a commercial purpose?

(G) To what extent has the fact that this chemical substance is manufactured for commercial purposes been revealed to others? What precautions have been taken regarding these disclosures? Have there been public disclosures or disclosures to competitors?

(H) Does this particular chemical substance leave the site of manufacture in any form, *e.g.*, as product, effluent, emission? If so, what measures have been taken to guard against the discovery of its identity?

(I) If the chemical substance leaves the site in a product that is available to the public or your competitors, can the chemical substance be identified by analysis of the product?

(J) For what purpose do you manufacture the chemical substance?

(K) Has EPA, another Federal agency, or any Federal court made any pertinent confidentiality determinations regarding this chemical substance? If so, please attach copies of such determinations.

(2) *Identification of claims.* If any of the information contained in the answers to the questions listed in paragraph (a)(1)(iii) of this section is asserted to be confidential, the submitter must clearly identify the information that is claimed as confidential by marking the specific information on each page with a label such as “confidential business information,” “proprietary,” or “trade secret.”

(b) *Information other than specific chemical identity.* Any persons submitting information under this part may assert a claim of confidentiality for information other than specific chemical identity. Any such confidentiality claims must be made at the time the information is submitted. Confidentiality claims will apply only to the information submitted

with the claim. Confidentiality claims cannot be made when a response field on a reporting form is left blank or designated as not known or reasonably ascertainable. Except as set forth in this section, information claimed as confidential in accordance with this subsection will be treated and disclosed in accordance with 40 CFR part 2. The following steps must be taken to assert a claim of confidentiality for information other than specific chemical identity. If no claim is asserted at the time the information is submitted, or if the following steps are not taken, EPA will consider the information as not subject to a confidentiality claim and may make the information public without further notice.

(1) *Substantiation of claims.* A person asserting a claim of confidentiality for information other than specific chemical identity must submit detailed written answers to the following questions at the time of submission, signed and dated by an authorized official.

(i) For what period of time do you request that the information be maintained as confidential, e.g., until a certain date, until the occurrence of a specified event, or permanently? If the occurrence of a specific event will eliminate the need for confidentiality, please specify that event.

(ii) Information submitted to the EPA becomes stale over time. Why should the information you claim as confidential be protected for the time period specified in your answer to question #1?

(iii) What measures have you taken to protect the information claimed as confidential? Have you disclosed the information to anyone other than a governmental body or someone who is bound by an agreement not to disclose the information further? If so, why should the information be considered confidential?

(iv) Is the information contained in any publicly available material such as the

Internet, publicly available databases, promotional publications, annual reports, or articles? If so, specify which.

(v) Is there any means by which a member of the public could obtain access to the information? Is the information of a kind that you would customarily not release to the public?

(vi) Has any governmental body made a determination as to the confidentiality of the information? If so, please attach a copy of the determination.

(vii) For each item or category of information claimed as confidential, *explain with specificity* why release of the information is likely to cause substantial harm to your competitive position. Explain the specific nature of those harmful effects, why they should be viewed as substantial, and the causal relationship between disclosure and such harmful effects. How could your competitors make use of this information to your detriment?

(viii) Do you assert that the information is submitted on a voluntary or a mandatory basis? Please explain the reason for your assertion. If you assert that the information is voluntarily submitted information, please explain whether the information is the kind that would customarily not be released to the public.

(ix) Whether you assert the information as voluntary or involuntary, please address why disclosure of the information would tend to lessen the availability to the EPA of similar information in the future.

(x) If you believe any information to be (a) trade secret(s), please so state and explain the reason for your belief. Please attach copies of those pages containing such information with brackets around the text that you claim to be (a) trade secret(s).

(xi) Explain any other issue you deem relevant.

(2) *Identification of claims.* If any of the information contained in the answers to the questions listed in paragraph (b)(1) of this section is asserted to be confidential, the submitter must clearly identify the information that is claimed as confidential by marking the specific information on each page with a label such as “confidential business information,” “proprietary,” or “trade secret.”

(3) *Certification statement for claims.* In submitting a claim of confidentiality, a person must certify the truth of the following four statements concerning all information which is claimed as confidential:

(i) My company has taken reasonable measures to protect the confidentiality of the information.

(ii) I have determined that the information is not required to be disclosed or otherwise made available to the public under any other Federal law.

(iii) I have a reasonable basis to conclude that disclosure of the information is likely to cause substantial harm to the competitive position of the person.

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

§710.39 Electronic filing.

(a) EPA will accept information submitted under this subpart only if submitted in accordance with this section. All information must be submitted electronically to EPA via CDX. Prior to submission to EPA via CDX, Notices of Activity and any associated information must be generated and completed using the e-NOA software module.

(b) Obtain instructions for registering in CDX as follows:

(1) *Website.* The CDX Registration User Guide is available at

https://www.epa.gov/sites/production/files/documents/cdx_registration_guide_v0_02.pdf. To register in CDX, go to <https://cdx.epa.gov> and follow the appropriate links.

(2) *Telephone*. Contact the EPA CDX Help Desk at 1-888-890-1995.

(3) *E-mail*. E-mail the EPA CDX Help Desk at HelpDesk@epacdx.net.

(c) Obtain instructions for using the e-NOA software module as follows:

(1) *Website*. Go to the EPA New Chemicals under the Toxic Substances Control Act website at <https://www.epa.gov/reviewing-new-chemicals-under-toxic-substances-control-act-tsca/how-submit-e-pmn> and follow the appropriate links.

(2) *Telephone*. Contact the EPA TSCA Hotline at 1-202-554-1404.

(3) *E-mail*. E-mail the EPA TSCA Hotline at TSCA-Hotline@epa.gov.

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