Prepublication Copy Notice:

The EPA Administrator signed the following *Federal Register* document on June 22, 2017:

Title: **TSCA Inventory Notification (Active-Inactive) Requirements**
Action: **Final Rule.**
FRL: 9964-22
Docket No.: **EPA-HQ-OPPT-2016-0426**

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

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ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 710

[EPA-HQ-OPPT-2016-0426; FRL-9964-22]

[RIN 2070-AK24]

TSCA Inventory Notification (Active-Inactive) Requirements

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: The 2016 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 establishing a retrospective electronic notification of chemical substances on the TSCA Inventory that were manufactured (including imported) for nonexempt commercial purposes during the 10-year time period ending on June 21, 2016, with provision to also allow notification by processors. EPA will use these notifications to distinguish active substances from inactive substances. EPA will include the active and inactive designations on the TSCA Inventory and as part of its regular publications of the Inventory. EPA is also establishing 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 nonexempt commercial purposes is expected to resume. On receiving forward-looking notification, EPA will change the designation of the pertinent chemical substance on the TSCA Inventory from inactive to active. EPA is establishing 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: This final rule is effective on **[***insert date of publication date in the* **Federal Register]**.

ADDRESSES: The docket for this action, identified by docket identification (ID) number EPA-HQ-OPPT-2016-0426, is available electronically at *http://www.regulations.gov* or in person at the Office of Pollution Prevention and Toxics Docket (OPPT Docket), Environmental Protection Agency Docket Center (EPA/DC), West William Jefferson Clinton Bldg., Rm. 3334, 1301 Constitution Ave. NW., Washington, DC. The Public Reading Room is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The telephone number for the Public Reading Room is (202) 566-1744, and the telephone number for the OPPT Docket is (202) 566-0280. Please review the visitor instructions and additional information about the docket available at *http://www.epa.gov/dockets*.

FOR FURTHER INFORMATION CONTACT: *For technical information contact*: Myrta R. Christian, Chemistry, Economics, and Sustainable Strategies Division (mailcode 7406M), 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. Who does this action apply to?

You may be affected by this action if you domestically manufactured, imported, or processed a chemical substance listed on the TSCA Chemical Substance Inventory for nonexempt commercial purpose during the 10-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 in the future a chemical substance listed on the TSCA Chemical Substance Inventory.

The following North American Industrial Classification System (NAICS) codes are not intended to be exhaustive, but rather provides a guide to help readers determine whether this action may apply to them:

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

In addition, the discussion in Unit II.A. describes in more detail which chemical substances will and will not be subject to reporting under this action. You may also consult the regulatory text in this document for further information on the applicability of exemptions to this rule.

Note that TSCA's statutory definition of “manufacture” includes importing. Accordingly, the regulatory definition of “manufacture” for this rule includes importation. Since “manufacture” is itself defined (in this rule and in TSCA) to include “import,” it is clear that importers are a subset of manufacturers. 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 rule will do so expressly.

B. What action is the Agency taking?

On January 13, 2017 (82 FR 4255, FRL-9956-28) (Ref. 1), EPA proposed procedural

reporting requirements for persons who manufactured (including imported) in the past or intend to manufacture in the future chemical substances on the TSCA Inventory (hereafter referred to as the “Inventory”). EPA received numerous public comments on the proposed rule. This final rule is based on that proposal and the consideration of the public comments received.

This TSCA section 8(b) rule requires electronic reporting of chemical identity from persons who manufactured a chemical substance for nonexempt commercial purpose during the 10-year time period ending on June 21, 2016. EPA will accept notices for substances that were processed during the same ten-year time period. EPA will use the chemical identity information obtained from this retrospective reporting to designate as active those substances on the Inventory for which notices were received. If no notice is received during this retrospective reporting for a substance subject to designation on the Inventory, then that substance will be designated as inactive.

This rule also requires electronic reporting of certain information from persons who in the future intend to manufacture or process an inactive substance on the Inventory for nonexempt commercial purpose. The information to be reported includes chemical identity and the date when manufacturing or processing is anticipated to resume. Upon receipt of such notices, EPA will change the designation on the Inventory from inactive to active.

This rule includes procedures for persons who co-manufacture or co-process a reportable chemical substance. These procedures will allow the submission of a single commercial activity notice where there has been co-manufacturing or co-processing of a particular volume of a substance. These procedures are similar to TSCA Chemical Data Reporting (CDR) rule requirements (40 CFR 711.22) when two or more persons are involved in a particular manufacture or import transaction.

This rule also includes a simplified procedure for filing a submission, including when specific chemical identity information is claimed to be confidential business information (CBI) by a supplier, and finalizes the proposed procedure for filing a joint submission. See response to Comment 14 in Unit III. EPA expanded its electronic reporting system to include a pick list from which persons can select chemicals for reporting. The pick list will include only reportable chemical substances and will not include CBI. Substances that are on the confidential portion of the Inventory will be listed on the pick list by EPA accession numbers and generic names, as they appear on public versions of the Inventory. In cases where specific chemical identity is claimed CBI by a supplier, a submitter can provide a single notice to EPA for a CBI substance if it has in its possession the corresponding non-CBI chemical identifiers (EPA accession number and generic name).

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

This rule also finalizes proposed changes to 40 CFR 710.3 definitions. These changes were proposed to conform the definitions applicable to these reporting requirements with those that apply to CDR rule requirements (definitions found at 40 CFR 704.3 and 711.3) and the submission of Premanufacture Notices (PMNs) (definitions found at 40 CFR 720.3). Finally, this

rule finalizes recordkeeping requirements as required by TSCA section 8(b)(9)(B). Records relevant to retrospective notification must be retained for a period of 5 years beginning on the last day of the submission period. Records relevant to forward-looking notification must be retained for a period of 5 years beginning on the day that the notice was submitted.

C. Why is the Agency taking this action?

TSCA section 8(b)(4)(A) requires EPA to issue a final rule for retrospective reporting by June 22, 2017. This rule will enable EPA to fulfill a statutory obligation to designate chemical substances on the Inventory as active or inactive in U.S. commerce. TSCA section 8(b)(5)(B) further establishes a forward-looking reporting requirement that goes into effect as soon as EPA designates inactive substances. This rule also establishes the procedural framework whereby manufacturers and processors will discharge their notice obligations under this section of TSCA.

This rule and designations under the rule are not intended to indicate conclusions about the risks of chemical substances on the Inventory. Nonetheless, the designation of a substance as active or inactive will be relevant to the Agency's prioritization of substances in U.S. commerce under TSCA section 6(b).

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

EPA is issuing this rule under TSCA section 8(b), 15 U.S.C. 2607(b). 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.

Under section 553(d) of the Administrative Procedure Act, 5 U.S.C. 553(d), the Agency may make a rule immediately effective “for good cause found and published with the rule.” EPA

finds that there is "good cause" to make this rule effective upon publication in the **Federal Register** because the deadline for manufacturers to submit retrospective reports under this rule is fixed by statute at "180 days after the date on which the final rule is published in the **Federal Register**." TSCA section 8(b)(4)(A)(i). Because the submission deadline is tied by statute to the date of the rule's publication, rather than the effective date of the rule, delaying the effective date of this rule would not afford any additional time for manufacturers to comply with reporting requirements. Rather, delaying the effective date of the rule would push back the *start* of the submission period for retrospective reporting, but not the *end* of the submission period (which remains fixed by statute), leaving manufacturers with a shorter period (less than 180 days) during which notices may be submitted. Thus, any impact on the regulated community of making the rule immediately effective is expected to be beneficial, given that an immediate effective date provides manufacturers with the greatest possible timing discretion regarding when to submit retrospective reports.

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

EPA has reevaluated the potential costs of establishing the reporting requirements for manufacturers and processors in response to comments received. This analysis, which is available in the docket, is discussed in Unit V. and briefly summarized here (Ref. 2).

During the retrospective (or "start-up") period, between approximately June 2017 and June 2018, typical costs per firm are estimated at $1,188 per submission (with an estimated eighteen chemicals per submission), with possible additional costs at $41.55 per CDX registration in the event that the submitter is not currently registered in CDX. Among manufacturers, an estimated 5,322 firms will undertake rule familiarization with 1,585 completing compliance determination, form completion, and recordkeeping. For manufacturers,

the total burden during start-up is estimated at 38,613 hours with an associated total cost of $3.09 million. For processors, an estimated 283,993 firms will undertake rule familiarization, with 100 completing compliance determination, form completion, and recordkeeping.

For processors completing rule familiarization only, the cost entails 3.30 hours on average per firm (under $300 per firm). For processors who complete a submission, typically involving one chemical, the burden for rule familiarization, compliance determination, form completion and recordkeeping during the start-up year is estimated at 500 hours with an associated cost of $0.04 million. Lastly, for 169 new CDX registrations (for individuals lacking previous experience with electronic reporting to EPA), burden during start-up is estimated at 90 hours with an associated cost of $0.007 million.

The rule has minimal burden and cost implications related to ongoing reporting with the typical cost per firm estimated at $889 per submission 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 225 burden hours per year with an associated cost of $17,779 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 Inventory. Associated costs are estimated at $3.62 million during start-up, and $0.22 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 $9.7 million per year using a 3% discount rate, and at $11.8 million per year using a 7% discount rate.

II. Summary of the Final Rule

EPA is describing in this unit the reporting requirements for manufacturers and processors of chemical substances pursuant to TSCA section 8(b). EPA developed two versions of a Notice of Activity (NOA) reporting form for submitting the information described in this rule for the two reporting scenarios, retrospective and forward-looking (Ref. 3). The Notice of Activity Form A (EPA Form No. TBD-1) will be used for retrospective reporting, and the Notice of Activity Form B (EPA Form No. TBD-2) will be used for forward-looking reporting.

EPA intends that the provisions of this rule be severable. In the event that any individual provision or part of the rule is invalidated, EPA intends that this would not render the entire rule invalid, and that any individual provisions that can continue to operate will be left in place.

A. What chemical substances and activities are reportable under this rule?

1. Reportable chemical substances. The retrospective reporting requirements of this rule apply to chemical substances listed on the Inventory that were manufactured for nonexempt commercial purposes during the 10-year period ending on June 21, 2016. This 10-year period, referred to here as the "lookback period," is set by statute. The forward-looking reporting requirements apply to substances listed as inactive on the Inventory that are to be reintroduced into U.S. commerce for nonexempt purposes. The Inventory is available at *https://www.epa.gov/tsca-inventory*.

2. Exemptions from reporting.

i. Excluded chemical substances. The scope of chemical substances covered under this rule is reflected in the definitions of "chemical substance subject to commercial activity designation," and "reportable chemical substance," at 40 CFR 710.23, which exclude substances that are not chemical substances and substances that are not listed on the Inventory. For example, a substance that is not considered a "chemical substance" (as provided in subsection 3(2)(B) of

TSCA and in the definition of “chemical substance” in 40 CFR 710.3(d)) is not a “chemical substance subject to commercial activity designation” or a “reportable chemical substance” and it thus cannot become an “active substance” or an “inactive substance.” A similar analysis applies with respect to a mixture (as defined in 40 CFR 710.3(d)), although individual Inventory-listed substances present in the mixture may be subject to reporting. Additionally, a substance that has not been added to the Inventory because it is manufactured solely under a TSCA section 5(h) exemption (*e.g.*, low releases and low exposures exemption, low volume exemption, polymer exemption, research and development exemption, test marketing exemption) is not a “chemical substance subject to commercial activity designation” or a “reportable chemical substance” and it cannot become an “active substance” or an “inactive substance.” See response to Comment 1 in Unit III.

Naturally occurring chemical substances also are excluded from reporting under this rule, as long as the manufacturing and processing of such substances meet the criteria set forth in 40 CFR 710.27(b). Naturally occurring substances are considered to be automatically included on the Inventory as the category “Naturally Occurring Chemical Substances” (42 FR 64578). EPA is designating the whole category of Naturally Occurring Chemical Substances as active substances by this rule, thereby excluding them from reporting under this rule.

ii. Manufacturing or processing for an exempt commercial purpose. Manufacturing or processing a chemical substance listed on the Inventory solely for an exempt commercial purpose is not subject to reporting requirements under TSCA section 8(b)(4) or 8(b)(5). The statute limits these notification obligations to manufacturing and processing for “nonexempt commercial purpose.” The scope of manufacturing or processing for an exempt commercial purpose is set forth in 40 CFR 710.27(a). While EPA expects that many chemical substances

manufactured or processed for exempt commercial purposes will not be listed on the Inventory (due to similar exemptions under PMN regulations), and therefore are already excluded from reporting under this rule, the activity exemptions listed at 40 CFR 710.27(a) clarify circumstances under which a person is exempt from reporting requirements for the manufacturing or processing of a chemical substance that has been listed on the Inventory (e.g., due to another manufacturer's actions). For example, the manufacturing or processing of impurities or byproducts that have no subsequent commercial purpose will not trigger reporting obligations under this rule. See 40 CFR 710.27(a)(3). Additionally, manufacturing or processing in small quantities solely for research and development is exempt as described in 40 CFR 710.3(d) and 40 CFR 710.27(a)(1). Furthermore, the import or processing of substances solely as part of articles is not subject to reporting under this rule. See 40 CFR 710.27(a)(2) and response to Comment 2 in Unit III. In response to comments, EPA revised the rule to clarify that manufacturing or processing a chemical substance solely for export from the United States or for test marketing purposes are also exempt commercial purposes not subject to reporting requirements under this rule. See 40 CFR 710.27(a)(4) and (5) and response to Comment 1 in Unit III.

iii. Chemical substances for which EPA already has an equivalent notice.

EPA is establishing an exemption from the retrospective reporting requirement for three different circumstances in which EPA has already received equivalent notice that a chemical substance was manufactured during the lookback period, and further requirement to submit a notice would therefore be inconsistent with TSCA section 8(a)(5)(B).

First, chemical substances that are on the interim list of active substances described in TSCA section 8(b)(6) will be designated as active substances, by operation of this rule, and they

are exempted from retrospective notification requirements under this rule. The interim list will be available on the TSCA Inventory web page (see *https://www.epa.gov/tsca-inventory*), and is comprised of all chemical substances reported in 2012 or 2016 under the CDR rule, 40 CFR part 711. See 82 FR 4259. A CDR notice from 2012 or 2016 provides equivalent notice to EPA that the substance was manufactured during the lookback period. In response to comments, this exemption now applies irrespective of whether the substance is on the confidential portion of the Inventory. See 40 CFR 710.23 for revised definition of "interim active substance" and response to Comment 3 in Unit III.

Second, chemical substances that were added to the Inventory during the ten-year time period ending on June 21, 2016, pursuant to a Notice of Commencement (NOC) under 40 CFR 720.102 received by the Agency between June 21, 2006 and June 21, 2016, will be designated as active substances, by operation of this rule, and they are exempted from retrospective notification requirements under this rule. An NOC is required to be submitted on or no later than 30 calendar days after the first day of manufacture for commercial purpose. Additionally, an NOC substance is considered to be added to the Inventory on the date the NOC is received by EPA, provided that the EPA determines the NOC to be valid during its review. Therefore, a processed NOC provides equivalent notice that the substance was manufactured or processed during the lookback period. This exemption applies irrespective of whether the substance is on the confidential portion of the Inventory. See 40 CFR 710.23 for revised definitions of "active substance," "chemical substance subject to commercial activity designation," and response to Comment 4 in Unit III.

Third, a manufacturer is exempt from the retrospective notification requirements under this rule, for a particular chemical substance, if the manufacturer has evidence in the form of a

CDX receipt, documenting EPA's receipt of an NOA Form A from another manufacturer. See 40 CFR 710.25(a) and response to Comment 6 in Unit III. Manufacturers should keep in mind, however, that they bear the risk of failing to submit a required forward-looking notification (NOA Form B) notice if they rely on this Form A exemption, and the Form A notice (for which they have a CDX receipt) is later withdrawn, leading to the substance being designated as inactive. Furthermore, one manufacturer's expectation that another manufacturer will *later* submit an NOA Form A is not an acceptable basis for relying on this exemption. Since it is only submitters who will be notified of errors, manufacturers relying on the exemption are responsible for assuring their substance is designated as commercially active.

iv. Inapplicability of exemptions to persons seeking to maintain an existing CBI claim for specific chemical identity. Persons who manufactured or processed a chemical substance on the confidential portion of the Inventory, that was added to the Inventory prior to June 22, 2016, should recognize that they must submit an NOA Form A to EPA if they wish to indicate that they "seek to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential." See TSCA 8(b)(4)(B)(ii) and response to Comment 3 in Unit III. This includes persons that, during the lookback period, manufactured or processed a confidential substance on the Inventory for which EPA already has an equivalent notice (as described in paragraph A.2.iii. of this Unit). It may also potentially include persons that, during the lookback period, manufactured or processed a confidential substance on the Inventory for an exempt commercial purpose (as described in paragraph A.2.ii. of this Unit), if such substance is designated active due, for instance, to EPA's receipt of an equivalent notice (such as an NOC or CDR report). In connection with extending manufacturers' reporting exemptions to cover substances on the confidential portion of the Inventory, EPA has revised 40 CFR 710.25(b) to

clarify manufacturers' and processors' discretion to report. If manufacturers elect not to submit a notice because they are availing themselves of one of the exemptions described above, then they are foregoing their opportunity to maintain an existing claim for protection against disclosure of the specific chemical identity of the substance as confidential. EPA is required, by statute, to move from the confidential to the public portion of the Inventory any active chemical substance for which no request is received to maintain an existing CBI claim for chemical identity. See TSCA section 8(b)(4)(B)(iv) and 40 CFR 710.37(a).

3. Chemical substances added to the Inventory on or after June 22, 2016. Chemical substances added to the Inventory on or after June 22, 2016 will be designated as active, by operation of this rule. Such substances are not subject to reporting under this rule. Furthermore, such substances are beyond the scope of the CBI claim maintenance provision under TSCA section 8(b)(4)(B)(ii). This CBI maintenance provision is intended to address "existing claim[s] for protection against disclosure of the specific chemical identity." EPA interprets this to be a reference to CBI claims asserted prior to June 22, 2016. See 40 CFR 710.23 for revised definition of "active substance."

B. When will reporting be required?

1. Retrospective reporting period for manufacturers. Manufacturers must report to EPA 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 will include the active designations, determined by the notices received, on a draft of the Inventory. EPA will publish this draft Inventory with the active designations as soon as is practicable following the close of the 180-day submission period for manufacturers. This draft

Inventory with active designations will not have the legal effect of actually designating any chemical substance as inactive. EPA, therefore, does not construe this draft Inventory as the list with "designations of active substances and inactive substances" (TSCA section 8(b)(5)(A)) from which forward-looking reporting commences (TSCA section 8(b)(5)(B)). EPA concludes that the statute is referring in both sections to the completed product of the initial cycle of sorting between active and inactive substances, not the preliminary product of the initial cycle of such sorting (*i.e.*, a draft Inventory released between manufacturer and processor reporting).

2. Retrospective reporting period for processors. Processors may report to EPA not later than 420 days after the final rule is published in the **Federal Register**. EPA originally proposed that processors may report not later than 360 days after the final rule is published in the **Federal Register**. EPA's rationale was that the additional 180-day time period for processors would allow processors to search EPA's publication of the draft Inventory with active designations, based on the retrospective reporting by manufacturers, and to report only those chemical substances not already reported. In response to comments received that the additional 180-day submission period for processors should begin on the date on which the draft Inventory is published, which EPA anticipates will likely occur approximately 60 days after the 180-day submission period for manufacturers closes, and to a comment that the rule should specify a fixed date on which the processor submission period will end, EPA is finalizing the rule such that processors may report not later than 420 days, rather than 360 days, after the final rule is published in the **Federal Register**. See 40 CFR 710.30(a)(2) and response to Comment 7 in Unit III.

Processors have the option to simply not report under TSCA section 8(b)(4) and continue processing until the effective date of EPA's designation of a chemical substance as inactive on

the Inventory. At such time, any further processing of the substance for a nonexempt commercial purpose, without prior notification to EPA, will be prohibited by TSCA section 8(b)(5). Earlier notification under TSCA section 8(b)(4) will allow EPA to add the substance to the Inventory as an active substance, so that processing can continue without the need for a later notification under TSCA section 8(b)(5).

3. Forward-looking reporting. The forward-looking reporting period begins on the effective date of EPA's final active/inactive substance designations. Manufacturers and processors intending to reintroduce into U.S. commerce for a nonexempt commercial purpose a chemical substance designated as inactive on the Inventory must report to EPA not more than 90 days before the anticipated date of manufacturing or processing. EPA originally proposed that forward-looking notices would be required to be submitted not more than 30 days before the date of manufacturing or processing. EPA agrees with commenters that notices should be submitted based on the anticipated (not actual) date of manufacturing or processing. EPA also finds that extending such submission period from 30 to 90 days prior to resuming manufacturing or processing will afford manufacturers and processors additional time to adjust to information and schedule changes and will not significantly impact the accuracy of notices submitted. See 40 CFR 710.29(c)(2), 40 CFR 710.30(b)(1), and response to Comment 8 in Unit III.

4. Transitional period reporting and effective date for inactive substance designations. The structure of the reporting requirements under TSCA sections 8(b)(4)(A) and 8(b)(5)(B) results in a transitional period beginning on June 22, 2016 (the day after the lookback period for retrospective reporting ends) and ending on the date that EPA designates chemical substances on the Inventory as active or inactive (the day that forward-looking reporting begins). It is possible that substances that were not manufactured or processed during the lookback period—and

therefore cannot be designated as active through retrospective reporting—may be reintroduced into U.S. commerce during this transitional period. In response to comments expressing concern that persons who began manufacturing or processing such substances during the transitional period might be obliged to curtail manufacturing or processing on the date that EPA publishes an inactive substance designation, or else find themselves in violation of the forward-looking notice requirement, EPA is establishing an effective date provision for the designation of a chemical substance as an inactive substance. As "inactive substance" is now defined, a substance is not designated as an "inactive substance" until 90 days after EPA has identified the substance for inactive designation. EPA will identify chemical substances for inactive designation in a signed action accompanying the first version of the Inventory with all finalized active-inactive listings. EPA expects to publish this first version of the Inventory with all listings identified as active or inactive as soon as practicable after compilation, in a posting on EPA's TSCA Inventory web page (see *https://www.epa.gov/tsca-inventory*). See 40 CFR 710.23 for revised definition of "inactive substance" and response to Comment 9 in Unit III.

Accordingly, the rule clarifies that the obligation to submit an NOA Form B does not arise until 90 days after EPA has identified chemical substances for the inactive designation. The rule also clarifies that manufacturers and processors will be permitted to submit an NOA Form B for a substance that EPA has identified for inactive designation, even before the effective date of such designation has arrived, and thus before the substance has the legal status of being inactive. Thus, persons manufacturing or processing a substance for nonexempt commercial purpose during the transitional period are afforded time to react to an inactive substance identification and are permitted to file an NOA Form B prior to the effective date of the substance being designated as inactive. Similarly, persons that anticipate reintroducing a substance into U.S.

commerce for nonexempt commercial purpose shortly after EPA identifies such substance as inactive are afforded time to react to an inactive substance identification and are permitted to file an NOA Form B prior to the effective date of the inactive designation, so long as such form is filed no more than 90 days before the anticipated date of manufacturing or processing. See 40 CFR 710.30(b)(2) and response to Comment 10 in Unit III.

C. What information will be reported?

1. Information reported by manufacturers during retrospective reporting. This rule will require that manufacturers reporting for the retrospective reporting period provide chemical identity information and indicate whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. In response to comments stating concern with burden associated with information required to be reported, EPA removed the proposed requirements to report commercial activity type and date range, as EPA determined these requirements are unnecessary to achieve the objective of designating substances as active or inactive on the Inventory. See 40 CFR 710.29(b) and response to Comment 11 in Unit III. In response to comments stating concern for availability of information required to be reported, EPA clarified that persons required to report under this rule will provide information to the extent it is known to or reasonably ascertainable by them. See 40 CFR 710.29(a) and response to Comment 12 in Unit III. In response to comments requesting that a manufacturer be able to correct or withdraw an NOA Form A in the event that it discovers errors in the notice, EPA is not establishing a formal corrections provision in the regulation, but will allow a manufacturer or processor to withdraw an NOA Form A, provided that the withdrawn notice is submitted prior to the end of the submission period for processors, *i.e.*, not later than 420 days after the final rule is published in the **Federal Register**. See response to Comment 13 in Unit III. The manufacturer

may effect a correction by filing a new NOA Form A following withdrawal, so long as the new Form A is filed within the time provided in the rule for the initial filing (i.e., no later than 180 days after the final rule is published in the Federal Register).

2. Information reported by processors during retrospective reporting. Processors that choose to report for the retrospective reporting period will be required to provide chemical identity information and whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. In response to comments received, EPA removed the proposed requirements to report commercial activity type and date range as these requirements were deemed unnecessary to achieve the objective of designating substances as active or inactive on the Inventory. See 40 CFR 710.29(b) and response to Comment 11 in Unit III. EPA is not establishing a formal corrections provision in the regulation for an NOA Form A, but will allow a processer to withdraw an NOA Form A, provided that the withdrawn notice is submitted not later than 420 days after the final rule is published in the **Federal Register**. See 40 CFR 710.30(a)(3) and response to Comment 13 in Unit III. As with manufacturers, processors can effectuate a correction by filing a new Form A within the time provided in the rule for the initial filing (i.e., no later than 420 days after the final rule is published in the Federal Register).

3. Information reported during forward-looking reporting. This rule will require that persons that intend to manufacture or process an inactive substance for nonexempt commercial purpose provide chemical identity information, the anticipated date of manufacturing or processing for nonexempt commercial purpose, and whether they seek to maintain an existing claim for protection against disclosure of a CBI chemical identity, if applicable. In response to comments, EPA removed the proposed requirement to report commercial activity type as this requirement was deemed unnecessary to achieve the objective of re-designating inactive

substances as active, and revised the date of manufacturing or processing for nonexempt commercial purpose from actual to anticipated date. See 40 CFR 710.29(c) and response to Comment 11 in Unit III. Persons that have already commenced manufacturing or processing for nonexempt commercial purpose (*e.g.*, during the transitional period prior to the effective date of a substance's inactive designation) may provide the most recent date of manufacturing or processing in lieu of an anticipated future date, if the forward-looking notice is submitted prior to the effective date of the substance's inactive designation. See 40 CFR 710.29(c).

EPA's proposed rule related the timing of the reporting to a future "actual date of manufacturing and processing." See 82 FR 4267. In response to comments about the need for greater flexibility regarding the timing of a forward-looking notice, under the rule the validity of the notice does not depend on whether the intended manufacturing or processing actually occurs by the anticipated date. Therefore, manufacturers or processors need not supplement a forward-looking notice with confirmation of whether the intended manufacturing or processing of the chemical substance actually occurred by the anticipated date. By the same token, EPA will designate such substances as active, irrespective of subsequent changes in the intentions of the submitter of the forward-looking notice. Consistent with the regulatory definition of "active substance," an inactive substance becomes an active substance "based on the receipt of a notice under this subpart," 40 CFR 710.23, and the factual basis for the notice is the *submitter's intent*, expressed at time of notification, to manufacture or process an inactive substance for a nonexempt commercial purpose within 90 days of notification. See 40 CFR 710.25(c) and 40 CFR 710.30(b)(2). This simplified approach reduces burdens for both submitters and EPA, is consistent with the statute, and furthers the orderly and efficient implementation of the Inventory. See TSCA section 8(b)(5)(B)(iii) (requiring EPA to take certain definite actions "on

receiving" the notice). With respect to substances re-designated as active for which the intended manufacturing or processing has not been actualized after an extended period of time and not corrected, EPA may later adjust the status of such substances, through procedures that would be established by future rulemaking, to further implement TSCA section 8(b)(5)(A).

Finally, in response to comment requesting that submitters be able to withdraw an NOA Form B if their intent to re-commence manufacture or process a chemical substance later changes, EPA is allowing a submitter to request to withdraw its NOA Form B, and EPA may do so, if EPA has not yet altered the Inventory status of the substance in response to the original submission (*i.e.*, EPA has neither re-designated the substance from inactive to active nor moved the substance from the confidential portion of the Inventory to the public portion Inventory as a result of a request in the original submission for a CBI claim to be withdrawn). Because another person may have commenced manufacturing or processing for non-exempt commercial purpose in reliance of a substance being re-designated as active, the rule does not allow for EPA to revert a substance re-designated as active back to inactive status based on a request to withdraw an NOA Form B, or for EPA to revert a non-CBI substance back to a CBI substance based on a request to withdraw a Form B. It would be burdensome and potentially impossible to implement such an approach. See 40 CFR 710.30(b)(3) and response to Comment 13 in Unit III.

4. Reporting forms. The NOA Form A will be used by manufacturers for the retrospective reporting period. It will also be used by processors who choose to report for the retrospective reporting period. The NOA Form B will be used by manufacturers and processors for forward-looking reporting, which includes reporting chemical substances reintroduced into U.S. commerce during the transitional period. For the sake of clarity, the final rule now defines the terms 'Notice of Activity Form A' and 'Notice of Activity Form B', consistent with the use of

these terms in the proposal. The new NOA forms are based on EPA's NOC form (Ref. 4), since the information required in an NOA form is the same or similar to the information in the NOC form.

D. How will information be submitted to EPA?

The rule requires electronic reporting similar to the requirements established in 2013 for submitting other information under TSCA (see 40 CFR 704.20(e)) and in accordance with section 3.2000 of 40 CFR part 3 (CROMERR) (Ref. 5). Submitters will 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 rule. EPA expects that electronic reporting will minimize time requirements, support improved data quality, and provide efficiencies for both the submitters and the Agency.

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. 6) The rule follows two previous rules requiring similar electronic reporting of information submitted to EPA for CDR and PMNs.

This rule will require persons submitting notices of activity to EPA under TSCA section 8(b) to follow the same electronic reporting procedures used for other TSCA submissions, *i.e.*, to register with EPA's CDX (if not already registered) and use CISS to prepare a data file for submission. Registration 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 TSCA submissions will be able to add the “Submission for Chemical Safety and

Pesticide Program" (CSPP) service to their current registration in CDX and use the CISS web-based reporting tool.

EPA developed the CISS for use in submitting data under TSCA sections 4, 5, 8(a), and 8(d) to the Agency electronically. The web reporting tool is available for use with Windows, iOS, Linux, and UNIX based computers and uses "Extensible Markup Language" (XML) specifications for the efficient transfer of data across the Internet when notices are submitted to EPA. CISS works with CDX to secure online communication, provides user-friendly navigation, creates a completed document in Portable Document Format (PDF) for review prior to submission, and enables information to be submitted easily in XML format or as PDF attachments.

The NOA forms described in this rule are 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.

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

E. How will CBI claims and requests be handled?

Notices pursuant to this rule 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. In response to comments received, EPA has extensively re-written the substantiation questions from the proposed rule in a manner intended to more succinctly secure responses for CBI assertions of discrete data elements as well as CBI concerns on the linkage of data elements. See 40 CFR 710.31 and response to Comment 17.

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, TSCA section 14(c)(3) and this rule require that all such claims be substantiated at the time of submission. EPA will review a representative subset of these claims as specified by TSCA section14(g)(1).

2. *Requests to maintain existing CBI claims for chemical identity*. Any manufacturer or processor submitting an NOA 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 listed on the confidential portion of the Inventory. EPA believes this is the correct interpretation of "a manufacturer or processor . . . that seeks to maintain an existing claim for protection against disclosure" of specific chemical identity in TSCA section 8(b)(4)(B)(ii). A number of manufacturers and processors may legitimately benefit from the confidential status of a specific chemical identity, even when such persons did not originally report that chemical identity to EPA and therefore were not in a

position to assert a CBI claim for that chemical identity. Congress could not have intended that such companies would be forced to rely on another company to request to maintain the claim. For example, the initial claimant may no longer exist or may no longer manufacture or process the chemical substance, or may simply fail to file the required NOA. 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 did not file under TSCA section 8(b)(4)(B)(ii).

Pursuant to TSCA section 8(b)(4)(B)(iv), EPA will move an active substance from the confidential portion of the Inventory to the non-confidential portion if no manufacturer or processor submitting an NOA under TSCA section 8(b)(4)(A) requests to maintain the existing CBI claim for the specific chemical identity of that chemical substance. See 40 CFR 710.37(a). As a courtesy, EPA practice is to notify original claimants and/or the public when it has moved substances from the confidential portion of the Inventory to the public portion of the Inventory, *e.g.*, through direct contact with the original claimant or publication of a **Federal Register** notice. A chemical substance for which EPA has received a request to maintain an existing CBI claim for specific chemical identity will remain on the confidential portion of the Inventory pending EPA's review of the claim pursuant to a review plan to be promulgated at a later date in accordance with TSCA section 8(b)(4)(C)-(D).

While this rule requires submitters to indicate whether they seek to maintain an existing CBI claim for specific chemical identity, this rule does not include mandatory substantiation requirements for CBI requests for specific chemical identity on an NOA Form A. TSCA section 8(b)(4)(B)(iii) stipulates that EPA shall "require the substantiation of those claims pursuant to

section 14 and in accordance with the review plan described in subparagraph C." EPA will be conducting a separate rulemaking to establish this review plan. The review plan will include mandatory requirements for substantiating a CBI request for specific chemical identity reported in an NOA Form A and specify when such substantiation is to be provided. If EPA receives an NOA Form A in which the submitter requests to maintain an existing CBI claim for specific chemical identity but chooses not to substantiate such at the time of filing, EPA will continue to list the chemical substance on the confidential portion of the Inventory pending the submission of any substantiation required under the review plan and EPA's review of the claim pursuant to the review plan.

However, in this rule the Agency is allowing companies to submit substantiation for the CBI claims for specific chemical identity at the same time that the NOA 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 substantiations will exempt the company from the requirement to submit additional substantiation under the terms of the review plan. See TSCA section 8(b)(4)(D). EPA will review requests to maintain CBI claims for specific chemical identity in accordance with the TSCA section 8(b)(4)(D) review plan in the timeframe mandated by TSCA section 8(b)(4)(E).

With respect to requests to maintain existing CBI claims that are submitted on an NOA Form B, TSCA section 8(b)(5)(B) stipulates that such requests must be substantiated not later than 30 days after submitting Form B. See TSCA section 8(b)(5)(B)(ii)(II). Substantiation requirements for NOA Form B CBI claims for specific chemical identity are found in 40 CFR 710.37(a)(2).

The Agency will allow companies to submit substantiation at the same time that their NOA Form B is filed, if they so choose. Persons submitting an NOA Form B may find it more efficient to provide the substantiation for a CBI claim for specific chemical identity at the time of filing.

III. Summary of Response to Comments Including Changes and Clarifications from the Proposed Rule

This unit summarizes EPA's responses to comments for several general areas from multiple stakeholders. EPA also discusses any changes to and clarifications from the proposed rule, and where responses are particularly relevant to the requirements of the final rule. A separate document that summarizes the comments relevant to the proposal and EPA's responses to those comments has been prepared and is available in the docket for this rulemaking (Ref. 7).

Comment 1: Several commenters indicated that EPA should clarify the activities for which notification is not required under the rule, and should confirm that all substances and activities that are exempt from premanufacture notification requirements are also exempt from reporting requirements under this rule. The commenters make reference to the following PMN exemptions: export-only exemption, low volume exemption, low releases/low exposures exemption, test marketing exemption, and polymer exemption. One commenter elaborated that substances exempted from listing on the TSCA Inventory and other substances exempt from premanufacture notification are exempt from this rule but are ambiguously stated as such. Two commenters elaborated that substances listed on the Inventory but manufactured under a low volume exemption should be exempt from reporting under this rule by a person manufacturing the substance under the exemption. One commenter recommended that all categories of substances for which no reporting is required pursuant to the CDR rule should be exempt from reporting under this rule.

Several commenters indicated that EPA should clarify or confirm that polymers are exempt from reporting under this action. One commenter requested that EPA clarify whether polymers manufactured under the pre-1995 polymer exemption rule need to be reported, as technically such polymers are listed on the Inventory. A few commenters stated that polymers listed on the Inventory, including polymers with a "Y" designation, should be included on the interim list of active substances. One commenter elaborated that polymers on the Inventory are not subject to CDR, that many were placed on the Inventory before EPA promulgated the TSCA section 5 polymer exemption rule and would likely meet the current standard for the polymer exemption, and that such low risk polymers should be on the interim active Inventory.

One commenter expressed concern that, without an explicit reporting exemption in the rule, a company manufacturing a chemical substance under a polymer, low volume, or test marketing exemption could inadvertently violate the reporting requirements if (without the company's knowledge) another company manufacturing the same substance added that substance to the confidential portion of the Inventory, then ceased manufacturing, causing the substance to be designated inactive. Another commenter expressed concern that, in the absence of an explicit reporting exemption in the rule for all companies manufacturing chemical substances under a PMN exemption, the rule would appear to require such companies to submit an inquiry to EPA to ascertain whether the chemical substances in question had been added to the confidential portion of the Inventory by another manufacturer.

Response: In response to the comment to clarify the reporting status under this rule of a substance manufactured under a TSCA section 5 exemption and not listed on the Inventory, EPA confirms that such substance is not subject to reporting under this action. The scope of chemical substances covered under this rule excludes substances that are not listed on the Inventory. See

definition of “reportable chemical substance” at 40 CFR 710.23. A substance that has not been added to the Inventory because it is manufactured solely under a PMN exemption is not a “reportable chemical substance” and, therefore, cannot become an “active substance” or an “inactive substance.”

EPA recognizes that in certain cases, chemical substances manufactured by a company under a PMN exemption may nevertheless be added to the Inventory voluntarily, or may subsequently be added to the Inventory by another company. Accordingly, in the proposed rule, EPA listed reporting exemptions for the following activities, which EPA construed as exempt commercial purposes: the manufacture or processing of a substance as described in 720.30(g) or (h), the manufacture or processing of a substance solely in small quantities for research and development, and the import of a substance as part of an article. EPA finalized the rule to include these exemptions and, based on comments, revised the rule to include additional exemptions: the manufacture or processing of a substance solely for test marketing purposes, and the manufacture or processing of a substance solely for export from the United States, except where the Administrator has made a finding described in TSCA section 12(a)(2). See 40 CFR 710.27(a)(4) and (5). EPA believes that these two additional activities also qualify as exempt commercial purposes based on the limited nature of these commercial activities and the exemptions from PMN reporting under TSCA sections 5(h)(1) and 12(a)(1) for substances manufactured solely for these purposes. While TSCA section 12(a)(1) authorizes EPA to include substances manufactured or processed solely for export in TSCA section 8 reporting, EPA construes manufacturing or processing solely for export to be an exempt commercial purpose, given that section 12(a)(1) broadly exempts such activities from other TSCA provisions, including PMN requirements under section 5.

EPA declined to add additional reporting exemptions in the final rule for activities that are exempt from PMN reporting based on rules promulgated under TSCA section 5(h)(4) (*i.e.*, low volume, low releases/low exposures, and polymer exemptions). EPA disagrees with comments that a substance manufactured under a TSCA section 5(h)(4) exemption but nevertheless listed on the Inventory should be exempt from reporting under this rule. EPA does not believe that manufacturing or processing under a low volume, low releases/low exposures, or polymer exemption (1984 or 1995 polymer exemption) qualify as exempt commercial purposes under TSCA section 8(b), despite the exemptions from reporting under TSCA section 5(h)(4) for such substances. This is because exemptions promulgated under section 5(h)(4) are predicated upon a risk determination, rather than the particular commercial purpose for which manufacturing is undertaken. Unlike the other activities that EPA has exempted from reporting requirements under this rule (*e.g.*, research and development, test marketing, export-only), the activities exempt from PMN reporting pursuant to rules promulgated under section 5(h)(4) need not be undertaken for any specific and limited commercial purpose. Because the commercial purpose for which a substance is manufactured is not integral to an exemption under section 5(h)(4), and in consideration of the statutory objective of TSCA section 8(b)(4)-(5) to enable EPA to determine which chemical substances on the Inventory are active in U.S. commerce, EPA does not construe activities undertaken pursuant to a section 5(h)(4) exemption to be exempt "commercial purposes" within the meaning of section 8(b)(4)(A)(i) and 8(b)(5)(B)(i). EPA emphasizes, however, that substances which (based on such PMN exemptions) have never been added to the Inventory are excluded from any reporting requirements under this rule.

EPA also disagrees with comments that this rule should provide reporting exemptions for polymers and other categories of Inventory-listed substances that are exempt from CDR for

reasons unrelated to the specific commercial purpose for which they are manufactured or processed. A statutory objective supported by reporting under this rule is to enable EPA to determine which chemical substances on the Inventory are active in U.S. commerce. This statutory objective under TSCA section 8(b) is distinct from the statutory objective for CDR under TSCA section 8(a). Whereas polymers and certain other categories of substances listed on the Inventory are exempt from reporting under CDR, these substances nevertheless require designation as active or inactive under TSCA section 8(b), and are therefore subject to reporting under this rule if they were or are anticipated to be manufactured for nonexempt commercial purpose. Exempting polymers and other categories of substances under this TSCA section 8(b) rule for no other reason than that they are exempt from CDR under TSCA section 8(a) would not accomplish the statutory objective of designating substances on the Inventory manufactured for non-exempt commercial purposes as active or inactive. EPA does not believe Congress intended for an entire category of substances (such as polymers), that were listed on the Inventory as of June 22, 2016, to be designated inactive despite the fact that such substances were manufactured or processed for wide-ranging commercial purposes during the 10-year lookback period.

EPA furthermore disagrees with comments that polymers should be included on the interim list of active substances. The interim list is defined by TSCA section 8(b)(6) to include only substances reported under CDR during the reporting period that most closely preceded the date of enactment of the TSCA amendments. Substances such as polymers that are exempt from reporting under CDR, therefore, are not eligible to be included on the interim list. Moreover, unless these substances were the subject of an NOC received during the lookback period, EPA has no equivalent notice that such substances were manufactured during the lookback period, and therefore no justification for designating the substances as active in this rule.

Finally, in response to comments expressing concern that a person manufacturing under a PMN exemption may be unaware that another person subsequently added the same substance to the confidential portion of the Inventory, EPA notes that it revised 40 CFR 710.25(a) and (c) to clarify that reporting is not required where it is not "known to or reasonably ascertainable by" a company that it manufactured a chemical substance subject to commercial activity designation during the lookback period, or that it intends to manufacture or process an inactive substance on the confidential portion of the Inventory. EPA anticipates that the presence of a substance on the confidential portion of the Inventory may be information that is not "known to or reasonably ascertainable by" a person who is operating under a PMN exemption and who did not submit the confidentiality claim for the specific chemical identity of that substance.

Changes to Activities that are Exempt from Reporting in the Final Rule: EPA revised the rule to exempt additional commercial activities from reporting requirements: the manufacture or processing of a substance solely for test marketing purposes, and the manufacture or processing of a substance solely for export from the United States, except where the Administrator has made a finding described in TSCA section 12(a)(2). See 40 CFR 710.27(a)(4) and (5).

Comment 2: One commenter stated that substances processed as part of an article should be exempt from reporting. One commenter indicated that substances contained within imported articles should be subject to reporting if and when they are released from the article during use and perform a separate end-use function.

Response: The proposed rule included an exemption from reporting requirements for persons importing a chemical substance as part of an article. EPA agrees with commenter that the processing of a chemical substance as part of an article should likewise be exempt from reporting under this rule on the grounds that it is processing for an exempt commercial purpose,

following the logic of the exemption for manufacture of a chemical as part of an article through import. Under TSCA, the import of a chemical substance as part of an article does not require new chemical reporting. Consequently, the Inventory does not list all chemical substances that are processed as part of articles since it does not include the processing of chemical substances as part of imported articles. More generally, the processing of a chemical as part of an article is not a basis to add a chemical substance to the Inventory. EPA believes it would be incongruous to identify a chemical substance as active solely based on the fact that it is processed as part of an article, when that would not be a basis to add the chemical substance to the Inventory in the first place if there were no manufacture reportable under TSCA section 5. In addition, EPA is concerned that an approach under which chemical substances are listed as active simply because they are components of articles that are processed in some fashion could undermine the purpose of meaningfully distinguishing active from inactive chemicals. It should be noted that the extraction of a chemical substance from an article would not be considered processing a chemical substance as part of an article and so would not be exempt from reporting under this provision. EPA therefore revised 40 CFR 710.27(a)(2) to exempt persons processing a chemical substance as part of an article from reporting requirements for that substance.

Regarding the comment that substances contained within imported articles should be subject to reporting if and when they are released from the article during use and perform a separate end-use function, no regulatory change is necessary. The final rule at 40 CFR 710.27(a)(2) refers to "[t]he import or processing of a chemical substance as part of an article." EPA's longstanding interpretation of this phrase is that a chemical substance is only considered to be imported "as part of an article" if the substance is not intended to be removed from that article and it has no end use or commercial purpose separate from the article of which it is a part.

See 42 FR 64583 (1977). Thus, for the kinds of articles from which a contained chemical substance would be released during use and perform a separate end-use function, the chemical substance would not be considered to be part of the article and would not qualify for exemption on that basis. In any event, as stated above, even in the case where a chemical substance is part of an article, the extraction of a chemical substance from an article would not be considered processing a chemical substance "as part of an article" and so would not be exempt from reporting on this basis. See also *TSCA Chemical Data Reporting Fact Sheet: Imported Articles,* available at *https://www.epa.gov/sites/production/files/2015-12/documents/cdr_fact_sheet_imported_articles_-_final_dec2015.pdf.* (Ref. 8)

Changes to Activities that are Exempt from Reporting in the Final Rule: EPA amended the rule to reflect that both importing and processing a chemical substance as part of an article are exempt from reporting requirements under this rule. See 40 CFR 710.27(a)(2).

Comment 3: Numerous commenters stated that CBI substances reported to the 2016 or 2012 CDR should be made active on the interim Inventory and should not be subject to retrospective reporting. Several commenters also stated that CBI substances reported to the 2016 CDR should also not be subject to further substantiation of CBI claims because the claims have already been substantiated.

Response: EPA agrees in part with the comments involving CBI substances. EPA confirms that it had proposed that both CBI and non-CBI substances reported to the 2012 or 2016 CDR would be made active on the interim list. EPA finalized this aspect of the rule. Furthermore, EPA revised the rule to reflect that both CBI and non-CBI substances reported to the 2012 or 2016 CDR will be eligible for exemption from retrospective notification requirements under this rule. See 40 CFR 710.23 and 710.25.

However, a company that seeks to maintain an existing CBI claim for specific chemical identity cannot avail itself of this exemption, and must submit an NOA Form A that includes such request, because TSCA section 8(b)(4)(B)(ii) requires a specific request to maintain the CBI claim. Pursuant to TSCA section 8(b)(4)(B)(iv), EPA must move to the non-confidential portion of the Inventory any active substance for which no request is received to maintain an existing CBI claim for specific chemical identity. EPA recognizes in the final rule that there may be circumstances where a company, which had previously sought a CBI claim for a specific chemical identity, may no longer view the CBI status as necessary or currently defendable. In such circumstance, the company may take advantage of any retrospective reporting exemption for which it is eligible, and decline to submit a retrospective notice to EPA.

Regarding substantiation, pursuant to TSCA section 8(b)(4)(D)(i), a previously submitted substantiation may satisfy the section 8(b)(4)(B)(iii) substantiation requirement if the prior substantiation was submitted to EPA within five years of a deadline to be established in the forthcoming review plan described in section 8(b)(4)(C)-(D). EPA does not expect that a 2012 CDR submission will satisfy the five-year substantiation requirement. Because the deadline for submitting substantiation in the review plan has not yet been set, EPA does not currently know whether substantiation submitted for a 2016 CDR submission will satisfy the TSCA section 8(b)(4)(B)(iii) five-year substantiation requirement. Note that a voluntary substantiation submitted with Form A might also not fall within the five-year period, depending upon the deadline that is set.

Changes to Chemical Substances That Are Exempt from Retrospective Reporting in the Final Rule: EPA changed the exemptions from retrospective reporting requirements to reflect that both CBI and non-CBI chemical substances reported to the 2012 or 2016 CDR will be

eligible. See 40 CFR 710.23 for revised definition of “interim active substance.” TSCA section 8(b)(4)(B)(ii) requires a notice to be submitted only by those manufacturers or processors that seek to maintain an existing CBI claim for the specific chemical identity of a reportable substance.

Comment 4: Several commenters stated that non-CBI substances added to the Inventory during the ten-year retrospective reporting period via an NOC should be exempt from notification.

Response: EPA agrees with this comment. An NOC is required to be submitted to EPA on or no later than 30 calendar days after the first day of manufacture of a new chemical substance for commercial purpose and an NOC substance is considered to be added to the Inventory on the date the NOC is received by EPA, provided that the EPA determines the NOC to be valid during its review. Requiring retrospective reporting of substances for which an NOC was received during the lookback period would be duplicative because EPA already has an equivalent report (the NOC itself) indicating that the substance was manufactured or processed during the lookback period. EPA furthermore concludes (consistent with its response to comments about the availability of the interim list exemption for CBI substances) that the analogous reasoning applies with respect to CBI substances added to the Inventory during the lookback period. EPA revised the rule to reflect that both CBI and non-CBI substances reported in an NOC during the lookback period will be eligible for exemption from retrospective notification requirements under this rule. EPA was able to compile this list of substances and designate them as active substances by the deadline for publication of the rule. EPA’s June 2017 posting of the Inventory will include these NOC substances designated as active (see *https://www.epa.gov/tsca-*

inventory). See 40 CFR 710.23 for revised definitions of “active substance” and “chemical substance subject to commercial activity designation.”

However, a company that seeks to maintain an existing CBI claim for specific chemical identity cannot avail itself of this exemption because TSCA section 8(b)(4)(B)(ii) requires a specific request to maintain the CBI claim. See response to Comment 3 for additional discussion on CBI substances.

Additionally, substantiation of a CBI claim for chemical identity submitted with an NOC may or may not satisfy the TSCA section 8(b)(4)(B)(iii) substantiation requirement. Pursuant to TSCA section 8(b)(4)(D)(i), a previously submitted substantiation may satisfy the section 8(b)(4)(B)(iii) substantiation requirement if the prior substantiation was submitted to EPA within 5 years of the deadline to be established in the forthcoming review plan described in section 8(b)(4)(C)-(D). NOCs submitted more recently may satisfy the 5-year substantiation requirement, while NOCs submitted earlier in the 10-year lookback period for retrospective reporting may not satisfy the 5-year substantiation requirement. Note that a voluntary substantiation submitted with an NOA Form A might also not satisfy the 5-year substantiation requirement, depending upon the deadline that is set in the review plan.

Changes to Chemical Substances That Are Exempt from Retrospective Reporting in the Final Rule: EPA added an exemption from retrospective reporting requirements for chemical substances added to the Inventory via an NOC during the ten-year retrospective reporting period. See 40 CFR 710.23 for revised definitions of “active substance” and “chemical substance subject to commercial activity designation.”

Comment 5: Several commenters stated that EPA should update the interim list and/or publish submissions frequently or in real time in order for potential submitters to see what is being submitted and to avoid or reduce duplicative submissions during retrospective reporting. *Response*: EPA has determined that publishing submissions frequently or in real time is not feasible. In order to publish notices frequently or in real time, EPA would need to develop, test, and implement an electronic platform that would be able transfer non-CBI notices from the Agency's confidential repository to a public system. EPA has not to date developed nor implemented such an electronic platform for TSCA purposes and does not believe that it could do so by the time it would be needed to support this action in a manner suggested by these comments. Additionally, because non-CBI notices suitable for publication would include those submitted with no CBI claims and those submitted with claims but for which CBI would be redacted, EPA would need to ensure that such an electronic platform would appropriately transfer only non-CBI notices to a public system. Furthermore, in order for published information to be accurate and reliable, EPA believes that notices would necessarily need to be fully processed and reviewed, which would not allow the Agency to publish notices in real time or even frequently, especially since the number of notices submitted may increase, possibly sharply, as the submission deadline approaches.

Comment 6: Several commenters disagreed with the proposal that each manufacturer must report every nonexempt chemical manufactured during the retrospective lookback period. Commenters stated that, for purposes of designating substances as active, EPA need only receive one notice for each reportable substance. Commenters elaborated that EPA should allow a "one-and-done" approach for retrospective reporting, i.e., once a notice is received by EPA for a particular substance, and either the notice is published and/or the interim list is updated and

published, other manufacturers need not report the same substance. One commenter stated that EPA appropriately proposed to require that each company that has manufactured a chemical substance on the Inventory during the lookback period must notify EPA of such manufacture. The commenter elaborated that "one-and-done" reporting is legally impermissible.

Response: EPA disagrees with the statement of one commenter that a "one-and-done" reporting exemption is impermissible under TSCA section 8(b)(4)(A)(i). Section 8(b)(4)(A)(i) states that the Administrator "shall require manufacturers . . . to notify the Administrator" of each chemical substance that the manufacturer has manufactured during the 10-year lookback period. The statute does not state that the Administrator shall require *all* manufacturers to submit such a notice. Had Congress intended to preclude the Administrator from implementing a "one-and-done" reporting process, Congress could have done so by specifying that the Administrator shall require *all* manufacturers to submit a notice for each chemical manufactured during the lookback period. Furthermore, EPA believes the commenter incorrectly discounts the significance of language in TSCA section 8(b)(4)(A)(i) admonishing EPA to issue the rule "subject to the limitations under subsection (a)(5)(A)." TSCA section 8(a)(5)(A) provides that "the Administrator shall, to the extent feasible . . . not require reporting which is unnecessary or duplicative." EPA does not agree with the commenter's assertion that subsection (a)(5)(A) is solely concerned with the manner of reporting, such that the scope of reporting would be unaffected. It is difficult to see how one could make a notification requirement less unnecessary or less duplicative except by tailoring the scope of persons who are required to submit the notification.

EPA agrees in part with the other commenters that a "one-and-done" approach should be allowed for retrospective reporting. Accordingly, EPA has revised the rule to exempt a

manufacturer from the retrospective notification requirements for a particular chemical substance, if the manufacturer has evidence in the form of a CDX receipt, documenting EPA's receipt of an NOA Form A from another manufacturer. As discussed further in Comment 5 in this Unit, it is infeasible for EPA to supply "real-time" reports to the public during the manufacturers' submission period for retrospective reporting by listing the particular substances for which it has already received an NOA Form A. However, manufacturers who possess an NOA Form A CDX receipt for a substance (*e.g.*, obtained through a consortium arrangement), documenting that an NOA Form A has already been received by EPA, may avail themselves of this exemption for that substance. Manufacturers should keep in mind, however, that they bear the risk of failing to submit a required forward-looking notification (NOA Form B) notice if they rely on this Form A exemption, and the Form A notice (for which they have a CDX receipt) is later withdrawn, leading to the substance being designated as inactive. Furthermore, one manufacturer's expectation that another manufacturer will later submit an NOA Form A is not an acceptable basis for relying on this exemption. If such an approach were allowed as a basis for exemption, then EPA would risk receiving no notification at all for an active substance, based on each manufacturer expecting that some other manufacturer would later submit an NOA Form A. Since it is only submitters who will be notified of errors, manufacturers relying on the exemption are responsible for assuring their substance is properly designated as commercially active.

However, a company that seeks to maintain an existing CBI claim for specific chemical identity cannot avail itself of this exemption because TSCA section 8(b)(4)(B)(ii) requires a specific request to maintain the CBI claim. See response to Comment 3 for additional discussion on CBI substances.

Changes to Chemical Substances That Are Exempt from Retrospective Reporting in the Final Rule: EPA added an exemption from retrospective reporting requirements in the rule for manufacturers that have evidence in the form of a copy of a CDX receipt documenting EPA's receipt of an NOA Form A from another person for the same chemical substance. See 40 CFR 710.25(a). However, as noted in Unit II and in 40 CFR 710.25(a), any manufacturer relying on another person's notice remains responsible for confirming that their substance becomes designated as active.

Comment 7: Several commenters requested that processors be allowed to report for an additional 180 days that begins when the draft Inventory is published and not when the 180-day submission period for manufacturers closes. One commenter questioned whether EPA had legal authority to extend the submission period for processors beyond 180 days, but accepted EPA's rationale for providing processors with additional reporting time after EPA's publication of the draft Inventory, provided that the extra time for processor reporting remains a short (i.e., no more than 180 days) and fixed period, as proposed.

Response: With respect to EPA's legal authority to establish a voluntary retrospective submission period for processors beyond 180 days, EPA believes this is implicit in its authority to establish a mandatory reporting period for manufacturers during the first 180 days. EPA notes that TSCA does not require that the rule impose any retrospective reporting requirements at all on processors. Nor does TSCA section 8(b)(4) establish a deadline for the publication of the Inventory designating active and inactive substances. Furthermore, allowing processors additional time to report is consistent with the manner in which the original Inventory was assembled, it advances the statutory objective of efficiently dividing active substances from inactive substances, and it advances the statutory objective under TSCA section 8(a)(5) of

avoiding (to the extent feasible) unnecessary reporting. Processors may be able to identify certain active substances that manufacturers would not, but requiring them to report during the same time period as manufacturers might lead them to duplicate the reports of manufacturers.

EPA originally proposed that processors may report not later than 360 days after the final rule is published in the **Federal Register**. EPA's rationale was that the additional 180-day submission period for processors, beyond the 180-day submission period for manufacturers, would allow processors to search EPA's publication of the draft Inventory with active designations, based on the retrospective reporting by manufacturers, and to report only those substances not already reported. EPA agrees with comments that the purpose of affording the additional 180 days for processors is best served if that 180-day submission period begins on the date on which processors would actually be able to review the draft Inventory. EPA also agrees with the comment that the rule should specify a fixed date on which the processor submission period will end, as originally proposed, but which would not be the case if the 180-day submission period were to begin on the unknown date of the publication of the draft Inventory. EPA intends to publish the draft Inventory with active designations as soon as is practicable following the close of the 180-day submission period for manufacturers, which is anticipated to be approximately 60 days after the 180-day submission period for manufacturers ends. Based on this anticipated timeframe for publishing the draft Inventory and in consideration of these comments, EPA is finalizing the rule to allow processors to report not later than 420 days after the publication of the rule in the **Federal Register**. See 40 CFR 710.30(a)(2). This revised submission period for processors provides a fixed date on which the processor submission period will end and is anticipated to provide an approximate 180-day period for processor reporting from the date by which EPA expects to publish the draft Inventory.

Changes to Processor Submission Period for Retrospective Reporting: EPA changed the retrospective reporting submission period for processors to end not more than 420 days after the publication of the rule in the **Federal Register**. See 40 CFR 710.30(a)(2).

Comment 8: Two commenters stated that an estimated date of re-commercialization should be able to be provided rather than an actual date. Two commenters stated that there is no need to limit the submission period for forward-looking reporting (NOA Form B) to not more than 30 days prior to manufacturing or processing, as proposed by EPA, citing that the statute only requires notification to take place "before" commercialization resumes. One commenter suggests that persons be permitted to submit an NOA Form B up to 90 days before re-commercialization instead of 30 days. Another commenter suggested that the Agency require an NOA Form B to be submitted not less than 90 days prior to manufacturing or processing to allow sufficient time for the Agency to evaluate the chemical and determine whether a Significant New Use Rule (SNUR) is needed. Another commenter was supportive of the proposed 30-day requirement.

Response: EPA agrees that the date that must be provided on an NOA Form B should be the anticipated date of reintroduction of a chemical substance in U.S. commerce, rather than the actual date. EPA recognizes that any reporting required in advance of actual commercialization is based on information and schedules that are subject to change, and providing an actual date of commercialization in advance, therefore, is not always practical. EPA believes that providing an anticipated date of commercialization should lessen concerns expressed by commenters. See 40 CFR 710.29(c)(2).

EPA has also decided to modify the date requirement from originally proposed, extending it to allow notice up to 90 days ahead of time, in addition to basing the date

requirement on the anticipated date of manufacturing or processing rather than the actual date of manufacturing or processing. EPA decided to retain some limitation on the submission period because EPA's experience with other reporting under TSCA (*e.g.*, PMNs) is that the earlier a notice is submitted, the higher the likelihood is that the schedule for commercialization will change or that a chemical substance might not be commercialized at all. EPA believes that retaining a limitation on the submission period for future reporting will reduce the number of notices submitted for substances whose schedule for commercial re-introduction changes appreciably. EPA also believes that extending the submission period to begin from 90 days, rather than 30 days, prior to resuming manufacturing or processing will afford manufacturers and processers additional time to adjust to information and schedule changes and will not significantly impact the accuracy of notices submitted. See 40 CFR 710.30(b)(1).

Regarding changing the deadline for submission of an NOA Form B to be at least 90 days prior to resuming manufacturing or processing for the purposes of Agency action (*e.g.*, SNUR), EPA disagrees with the commenter's interpretation that by requiring advance notification, Congress wanted to provide EPA an opportunity to take action to delay the resumption of manufacturing or processing if it had concerns about the subject chemical. To the contrary, the statute clearly reflects that the obligation to submit a section 8(b)(5)(B) notification was not intended as a tool to impede the resumption of manufacturing or processing. Specifically, the statute does not authorize EPA to structure the rule in such a manner that if a manufacturer or processor submits an NOA Form B, the manufacturer or processor could be obliged to wait longer than the next day to commence manufacturing and processing the chemical substance. See TSCA section 8(b)(5)(B)(i). EPA believes the most plausible explanations for why Congress imposed the advance notification requirement were: (1) to ensure that EPA actually receives the

notices (by making the lawful resumption of manufacturing or processing contingent on the notification) and; (2) to support EPA's subsequent prioritization efforts under TSCA section 6(b). See TSCA section 8(b)(5)(B)(iii)(IV).

Changes to the Date Requirement for Forward-looking Reporting: EPA changed the limitation on submitting an NOA Form B to be not more than 90 days prior to the anticipated date of manufacturing or processing. See 40 CFR 710.29(c)(2) and 40 CFR 710.30(b)(1).

Comment 9: *A few commenters asked EPA to clarify in the rule how it would implement the requirements of TSCA section 8(b)(7). For example, commenters requested that EPA confirm in the final rule when the draft and final lists of active and inactive substances will be published. One commenter indicated that EPA should identify all substances on the Inventory as active or inactive not later than 15 months after promulgation of this final rule. Another commenter indicated that EPA should publish an updated version of the Inventory, with all substances designated as active or inactive, not later than six months after the completion of the retrospective notification process. Commenters also stated that EPA should specify in the rule the date when substances will be designated as inactive. One commenter stated that EPA should publish a* **Federal Register** *notice every 90 days listing all substances that EPA has designated as active following receipt of an NOA Form B.*

Response: TSCA section 8(b)(7) requires EPA to make active and inactive designations available to the public, but it gives EPA discretion as to the manner and timing of doing so. EPA intends to publish a draft Inventory as soon as practicable after the close of the 180-day submission period for manufacturers, which will include only active designations (based on interim list designations, NOCs, and manufacturer reporting); chemicals that have no designation on this draft Inventory should not be assumed to be inactive. EPA intends to publish the first Inventory

identifying both active *and* inactive substances as soon as practicable after the close of the retrospective submission period for processors, in a web posting of the Inventory on EPA's Inventory web page (see *https://www.epa.gov/tsca-inventory*). Given that the statute does not mandate a specific deadline for the publication of the first Inventory identifying both active and inactive substances, and given the challenges of foreseeing precisely how much time will be necessary to review and compile the data it will receive from retrospective reporting, EPA has chosen not to impose a regulatory deadline on the publication of this first Inventory.

The obligation to submit an NOA Form B under TSCA section 8(b)(5)(B)(i) does not arise until a chemical substance has been "designated as an inactive substance." EPA is establishing an effective date provision for the designation of a substance as an inactive substance. EPA revised the rule so that an "inactive substance" designation becomes effective 90 days after the date that EPA identifies the substance for inactive designation. See 40 CFR 710.23 for revised definition of "inactive substance." EPA will identify substances for inactive designation in a signed action accompanying the first version of the Inventory with all active-inactive listings following the close of the retrospective submission period for processors. EPA intends to publish this signed action together with the Inventory in a web posting on EPA's Inventory web page (see *https://www.epa.gov/tsca-inventory*).

With respect to Inventory updates based on forward-looking reporting, the statute does not specifically require that EPA inform the public of the reintroduction of chemical substances by issuing **Federal Register** notices every 90 days, indicating what substances (if any) have been reactivated. EPA intends to include substances submitted in forward-looking notices and re-designated as active on the Inventory in its regular publications of the Inventory, which occur approximately every six months.

Changes to the Final Rule to Establish the Date When a Chemical Substance Will Be Designated as Inactive: EPA revised the rule so that an inactive substance designation is not effective until 90 days after the date that EPA identifies a substance for inactive designation. See 40 CFR 710.23 for revised definition of "inactive substance."

Comment 10: A few commenters expressed concerns about the status of substances manufactured or processed in the period between June 22, 2016 and the date the first Inventory with active and inactive designations is finalized and published. These commenters requested that EPA clarify the status of such substances.

Response: EPA clarified the status of these chemical substances in Unit II and the final rule. The structure of the reporting requirements under TSCA sections 8(b)(4)(A) and 8(b)(5)(B) results in a transitional period beginning on June 22, 2016 (the day after the lookback period for retrospective reporting ends) and ending on the date the forward-looking reporting period begins (*i.e.*, the effective date that chemical substances are designated as inactive, which is 90 days after EPA publishes the first Inventory with listings identified as active or inactive). A person who did not manufacture or process a particular chemical substance during the lookback period (June 21, 2006 through June 21, 2016) is not subject to the retrospective reporting provisions of this rule with respect to that substance, and should not submit an NOA Form A for that substance regardless of whether the person manufactured or processed the substance on or after June 22, 2016. If that substance is ultimately designated by EPA as inactive, however, any person who intends to manufacture or process that substance after it is designated as inactive must submit an NOA Form B.

To address concerns about substances reintroduced into U.S. commerce during the transitional period and potential interruptions in commercial activity that could arise upon EPA's

designation of such substances as inactive, EPA revised the rule to reflect that an inactive designation only becomes effective 90 days after EPA identifies the substance for such designation. EPA is clarifying that the obligation to submit an NOA Form B does not begin until the effective date of an inactive substance designation. Because EPA revised the rule so that an inactive substance designation is not effective until 90 days after the date that EPA identifies a substance for inactive designation, manufacturers and processors are afforded time to react to an inactive substance identification. Persons who are already manufacturing or processing a substance for nonexempt commercial purpose (*e.g.*, during the transitional period), and wish to continue doing so without interruption after EPA's designation of such substance as inactive, are permitted to submit an NOA Form B for such substance prior to the effective date of the inactive designation, which is the date that the substance attains the legal status of being inactive. Similarly, persons that anticipate reintroducing a substance into U.S. commerce for nonexempt commercial purpose shortly after EPA identifies the substance for inactive designation are also afforded time to react to the inactive substance identification and are permitted to file an NOA Form B prior to the effective date of the substance's inactive designation, as long as such form is filed no more than 90 days before the anticipated date of manufacture or processing. Manufacturers should be aware that the timely filing of an NOA Form B does not remedy an earlier failure to comply with the retrospective reporting requirement; it merely ensures that the manufacturer will not also be in violation of the forward-looking reporting requirement.

Changes to the Final Rule to Clarify the Status of Chemical Substances Manufactured or Processed in between the Retrospective and Forward-Looking Reporting Periods: EPA revised the rule to clarify that manufacturers and processors are permitted to submit an NOA Form B for a chemical substance that EPA has identified for inactive designation, even though the effective

date of such designation has not yet arrived, and thus the substance does not yet have the legal status of being inactive. See 40 CFR 710.30(b)(2).

Comment 11: Numerous commenters stated that certain data requirements should be eliminated or reduced. Two commenters stated that EPA should reduce the proposed requirement for a date range from retrospective notification by not requiring exact dates for the date range for retrospective notification, and instead suggested that the first and last dates of the range be reported by month and year. Numerous commenters stated that EPA should eliminate the proposed requirement for a date range from retrospective notification, indicating that such information would be burdensome to retrieve and evaluate and, in certain cases, may not be available due to record retention policies. Commenters further indicated that such information is not required to meet the statutory objective and that the certification statement should be sufficient to support data accuracy. Similarly, several commenters also stated that EPA should eliminate the proposed requirement for type of commercial activity from retrospective notification; one commenter indicated that the proposed requirement should also be eliminated from forward-looking notification. A few commenters suggested reducing the proposed requirement for type of commercial activity from retrospective notification by combining "Domestically manufactured" and "Imported" into one category for reporting. One commenter was supportive of requiring type of commercial activity.

Response: EPA has decided not to require date range and activity type for retrospective notification. EPA had proposed such information to serve the objective of verifying and validating notices submitted. However, in response to comments received, EPA has been persuaded that the collection of a date range of manufacture, as well as the collection of information to differentiate between domestic manufacture, import, and processing, is

unnecessary to serve the underlying objective of reliably differentiating active and inactive substances. EPA is also mindful that TSCA section 8(b)(4)(A)(i) specially admonishes the Agency to avoid, to the extent feasible, the collection of unnecessary information in this rule. As an alternative to requiring date and information, EPA has revised the NOA Form A certification statement to require an affirmation that manufacturing or processing of the chemical substance occurred during the lookback period. If EPA needs to verify the basis for such a certification, it can obtain and evaluate the documentation that submitters are required to maintain under 40 CFR 710.35.

EPA has similarly removed the activity type requirement for forward-looking notification. This is consistent with the evidence of Congressional intent motivating the notification requirement. See S. Rep. 114-67 at 20 (purpose is to categorize the chemical substances on the Inventory as "active or inactive," and "[m]anufacturers of an inactive substance may return the substance to the active inventory with a simple notification to EPA"). In response to comments received, EPA has been persuaded that information on activity type is not necessary to accomplish the purpose of the rule regarding differentiating inactive substances from active substances. EPA has also revised the NOA Form B certification statement to require an affirmation that persons submitting an NOA Form B have forward-looking intent to manufacture or process for nonexempt commercial purpose. If EPA needs to verify the basis for such a certification, it can obtain and evaluate the documentation that submitters are required to maintain under 40 CFR 710.35.

Changes to Required Reporting Elements in the Final Rule: EPA removed the date range and commercial activity type requirements from retrospective notification, and revised the certification statement on the NOA Form A to clarify that persons submitting the form are

certifying that manufacturing or processing of the chemical substance occurred during the lookback period. EPA also removed the commercial activity type requirement from forward-looking notification, and revised the certification statement on the NOA Form B to clarify that persons submitting the form are certifying that they have forward-looking intent to manufacture or process the substance. See 40 CFR 710.29(b) and 40 CFR 710.29(c).

Comment 12: Numerous commenters stated that EPA should clarify the meaning of "known or reasonably ascertainable," particularly in the context of scenarios involving mergers and acquisitions (e.g., corporate predecessors and successors) that occurred during or after the ten-year reporting period, and in such scenarios, who is responsible for reporting under the rule. Some commenters further elaborated that if a company no longer has a legal obligation to retain particular records, or if the records are no longer in the possession of the company (e.g., they are not available due to company document retention policies or are in the possession of an acquiring company), the information should be considered to be not "Known or Reasonably Available/ Ascertainable" and reporting should not be required. One commenter suggested amending 40 CFR 710.25 to add a new paragraph (b) to address entities formed during the lookback period that may not have historical records in their possession or control. Another commenter stated that EPA's proposal was still silent as to the level of diligence that must be used to determine which substances must be reported under NOA Form A and Form B, and suggested that EPA assign a "readily obtainable" standard to that level of diligence for the Form A's.

Response: CFR 40 Part 704 defines "Known to or reasonably ascertainable by" as 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. In response to commenters'

request for clarification of possession or control as it relates to corporate mergers and acquisitions, EPA has added to 40 CFR 710.23 the definition of “Possession or Control” from 40 CFR 704.3. Consistent with its use in Part 704, “Possession or Control” is defined as meaning in the possession or control of any person, or of any subsidiary, partnership in which the person is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the person in the research, development, test marketing, or commercial marketing of the chemical substance in question. Information is in the possession or control of a person if it is: (1) in the person's own files including files maintained by employees of the person in the course of their employment, (2) in commercially available data bases to which the person has purchased access, or (3) maintained in the files in the course of employment by other agents of the person who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

EPA believes it is appropriate to construe what “a reasonable person similarly situated might be expected to possess, control, or know,” based on the totality of pertinent factors. Prior loss of records consistent with document retention policies and the other individual factors cited by the commenters could be pertinent in construing what information is known or reasonably ascertainable, but they are not replacements for the regulatory standard. In any event, if a person actually knows information, then it is known or reasonably ascertainable.

In the context of the CDR rule, EPA has published extensive guidance on the application of the “known to or reasonably ascertainable by” standard and how to address retrospective reporting in the case of corporate succession. See, *e.g.*, *TSCA Chemical Data Reporting Fact Sheet: Reporting After Changes to Company Ownership or Legal Identity*, available at

https://www.epa.gov/sites/production/files/2015-05/documents/cdr_fact_sheet_company_changes.pdf (Ref. 9). See also 2*016 Chemical Data Reporting Frequent Questions*, available at *https://www.epa.gov/sites/production/files/2016-07/documents/cdr_fq_final_july_11_2016.pdf* (Ref. 10). EPA finds that guidance issued on these topics in the context of the CDR rule is also instructive in the context of this rule.

EPA agrees with one commenter that the level of diligence that must be used to determine which chemical substances must be reported using an NOA Form A should be clarified, but disagrees with the suggestion that manufacturers need not report their manufacture of substances during the lookback period if the knowledge that they conducted the prior manufacture is reasonably ascertainable by them but not "readily obtainable" by them. EPA revised 40 CFR 710.25(a) to clarify that if it is not "known to or reasonably ascertainable by" a manufacturer that the person manufactured a particular substance during the lookback period, then the person is not obligated to report that substance on an NOA Form A. EPA believes that the authority to limit retrospective reporting to information that is known or reasonably ascertainable at the time of the reporting obligation is implicit in the grant of rulemaking authority under TSCA section 8(b)(4), consistent with TSCA section 8(a) and the overall statutory objectives of TSCA section 8(b), and consistent with past practice for retrospective reporting on the CDR rule. The commenter set forth little basis for adopting a "readily obtainable" standard and EPA continues to believe (see proposal at 82 FR 4256) that it is appropriate to base this rule on basic reporting concepts that the public is already familiar with from the CDR. It would be confusing to have one standard governing the need to submit an NOA Form A ("readily obtainable") and another standard ("known to or reasonably ascertainable by") governing the information elements that need to be reported on the NOA Form A. Finally, EPA

has already significantly addressed commenters' broader concern about the potential burden of conducting an information search by eliminating the requirement to report the specific start and end dates of manufacture.

EPA also disagrees with one commenter that 40 CFR 710.25 should be amended to specifically address entities formed during the lookback period that do not have historical records in their possession. The revision to 40 CFR 710.23 to add the definition of "Possession or Control," and the revision to 40 CFR 710.25(a) to clarify application of the "known to or reasonably ascertainable by" standard in the context of retrospective reporting, apply to all persons subject to reporting under 40 CFR 710.25(a). It is not necessary to separately address a specific type of entity, *e.g.*, entities formed during the lookback period, in 40 CFR 710.25.

With respect to the standard of diligence for determining whether a chemical substance is subject to forward-looking reporting on an NOA Form B, EPA revised 40 CFR 710.25(c) to clarify that if it is not "known to or reasonably ascertainable by" a person that the substance being manufactured or processed is listed on the confidential portion of the Inventory as an inactive substance, then the person is not obligated to report that substance on an NOA Form B. This may be the case, for instance, if one person manufactures a polymer under a PMN exemption, but another manufacturer subsequently adds the same polymer to the confidential portion of the Inventory and then ceases manufacturing before the lookback period, resulting in the confidential substance being designated inactive. EPA anticipates that only persons operating under PMN exemptions will be able to avail themselves of this revision, since other persons will have no basis to manufacture an Inventory chemical without knowing the Inventory identity of the chemical.

With respect to the information that must be reported on an NOA Form B, believes that

the question of the information reporting standard and the standard of diligence has become moot, with the elimination of all information submission requirements other than those that EPA can reasonably expect the submitter to know. By direct operation of the statute and consistent with proposed procedural rules at 40 CFR 710.25, any person who intends to manufacture or process an inactive substance, except for a nonexempt commercial purpose, must submit an NOA Form B alerting EPA to "designate the applicable chemical substance as an active substance." TSCA section 8(b)(5)(B). Thus, irrespective of any rulemaking, TSCA itself requires the identity of the substance to be placed on the active Inventory to be specified. The proposed requirement to report the type of intended commercial activity has been eliminated, along with the "actual date" by which the inactive substance is to be manufactured or processed. If a person does not know the date by which it *anticipates* that the inactive substance is to be manufactured or processed, then filing NOA Form B would be inconsistent with the timing requirements of 40 CFR 710.30. Finally, EPA can reasonably expect the submitter to know its own identity. Accordingly, EPA has removed, as moot, the proposed specification in 40 CFR 710.29(c) that a person required to submit information on an NOA Form B must report information to the extent that such information is known or reasonably ascertainable by that person.

Changes to the Final Rule to Clarify "Known or Reasonably Ascertainable" and to Add a Definition for "Possession or Control:" EPA added a definition for "Possession or Control" in the rule to clarify the existing definition of "Known to or reasonably ascertainable by." See 40 CFR 710.23. EPA also revised 40 CFR 710.25(a) to clarify that if it is not "known to or reasonably ascertainable by" a manufacturer that the person manufactured a particular chemical substance during the lookback period, then the person is not obligated to report that substance on an NOA Form A. EPA revised 40 CFR 710.25(c) to clarify that if it is not "known to or

reasonably ascertainable by" a person that the substance being manufactured or processed is listed on the confidential portion of the Inventory as an inactive substance, then the person is not obligated to report that substance on an NOA Form B. EPA removed, as moot, the proposed specification in 40 CFR 710.29(c) that a person required to submit information on an NOA Form B must report information to the extent that such information is known to or reasonably ascertainable by that person.

Comment 13: Numerous commenters stated that EPA should provide a reasonable opportunity or a formal process to amend or correct retrospective notices. Several commenters suggested a time frame for corrections, e.g., up until the date that the first Inventory with active and inactive designations is published; for manufacturers, during the additional 180-day submission period for processors; and for processors, 180 days from the date that the first Inventory is published. Two commenters stated that EPA should also allow forward-looking notices to be corrected or rescinded. Several commenters indicated that corrections should be non-punitive.

Response: EPA agrees in part with these comments. The 180-day retrospective submission period for manufacturers is the maximum time provided for by the statute. While EPA is not providing a formal corrections process for retrospective reporting to the regulatory text, EPA will allow retrospective reporting notices submitted by manufacturers during the 180-day submission period for manufacturers to be withdrawn not later than 420 days after the publication of the final rule in the **Federal Register**. EPA will allow retrospective reporting notices submitted by processors during the 420-day submission period for processors to be withdrawn not later than [420 days after the publication of the final rule in the **Federal Register**], should processors discover errors in their original notices. See 40 CFR 710.30(a)(3).

With respect to forward-looking reporting, EPA is not providing a formal corrections process but has revised the regulatory text to allow forward-looking reporting notices submitted by manufacturers or processors to be withdrawn if EPA has not yet altered the Inventory status of the chemical substance in response to the original submission (*i.e.*, EPA has neither re-designated the substance from inactive to active nor moved the substance from the confidential portion of the Inventory to the public portion of the Inventory as a result of a request in the original submission for a CBI claim to be withdrawn). See 40 CFR 710.30(b)(3). Because a forward-looking notice will be processed even if the intended manufacture and processing does not occur as originally anticipated, and because it would be burdensome and potentially impossible to implement such an approach, the rule does not allow for EPA to revert a re-activated substance back to inactive status based on a request to withdraw a Form B, or for EPA to revert a non-CBI substance back to a CBI substance based on a request to withdraw a Form B.

EPA appreciates that retrospective withdrawals should be non-punitive. However, after the period allowed for withdrawal, incorrect information would be considered a prohibited act under Section 15(1) and 15(3). Similarly, incorrect information in forward-looking notices would also be considered a prohibited act under Section 15(1) and 15(3), if not withdrawn prior to EPA altering the Inventory status of the chemical substance in the original notice. Persons making corrections after these retrospective and forward-looking timeframes and seeking future penalty mitigation considerations may disclose within 21 days after they have an objectively reasonable basis for believing that a violation has, or may have, occurred, pursuant to EPA's Self-Disclosure policies. See: *https://www.epa.gov/compliance/epas-edisclosure*.

Changes to the Final Rule to Allow Withdrawal of a Notice of Activity Form A or Form B: EPA revised the rule to allow retrospective notices to be withdrawn if done so not later than [420

days after the date on which the final rule is published in the **Federal Register**]. See 40 CFR 710.30(a)(3). EPA revised the rule to allow forward-looking notices to be withdrawn if EPA has not yet altered the Inventory status of the substance in response to the original submission. See 40 CFR 710.30(b)(3).

Comment 14: A few commenters requested clarification on the proposed procedures for joint submissions. One commenter requested that EPA provide a different reporting option that avoids the need for a joint submission. Two commenters requested clarification on the reporting responsibilities of manufacturers, importers, and processors when a supplier fails to submit its information.

Response: EPA proposed procedures for joint submissions that will enable a company to submit a commercial activity notice for a chemical substance on the confidential portion of the Inventory in situations where the submitter does not know the specific chemical identity of the substance because a portion of the specific chemical identity is held CBI by a supplier. This rule includes such joint submission procedures that allow the submitter to provide information on the specific chemical identity that it has in its possession, and the supplier to separately provide information on the specific chemical identity that it has in its possession, in a manner that protects the supplier's CBI from the submitter of the NOA.

Additionally, since publication of the proposed rule, EPA expanded its electronic reporting system to include a pick list from which persons can select chemicals for reporting. The pick list will include only reportable substances and will not include CBI. Non-CBI substances will be listed by CASRNs and CA index names, as they appear on the Inventory, and CBI substances will be listed by EPA accession numbers and generic names, as they appear on public versions of the Inventory. Submitters can identify substances from the pick list and,

therefore, do not have to manually enter chemical identity information. Because the chemical identity information selected from the pick list and transmitted on the NOA form will not be CBI, there is no need for submitters who use this pick list to supply CBI to EPA. In cases involving third party CBI, a submitter can provide a single notice to EPA for a CBI substance, provided they have in their possession the corresponding non-CBI chemical identifiers, EPA accession number and generic name, by selecting the non-CBI identifiers from the pick list, thereby avoiding the need for a joint submission. If a submitting company does not know the EPA accession number and generic name, they can use existing mechanisms (*e.g.*, Inventory Correspondence) to request such information from EPA.

A submitting company that does not know the CBI chemical identity of the substance that it is required to report because of third party CBI, therefore, has two options for reporting. Such submitter can utilize the joint submission functionality in the electronic reporting tool. Alternatively, such submitter can select from the pick list based on the corresponding non-CBI chemical identifiers, EPA accession number and generic name, provided they have this information.

Changes to Reporting Options for Joint Submissions: EPA revised the final rule to add a description of the pick list that will be provided in the electronic reporting system and which can serve as an alternative to a joint submission, should submitters have in their possession non-CBI chemical identifiers (EPA accession number and generic name) for a reportable CBI substance.

Comment 15: A few commenters stated that the estimated reporting burden and costs are too low or unrealistic, citing the following universe estimates as underestimated: number of chemicals that are not reported under CDR because of exemptions or reporting threshold (including ten percent basis for nonexempt low volume chemicals and polymers) and total

burden for processors. One commenter recommended that EPA revise the number of processors or better explain the origins of EPA's estimation of 161,000 affected processors. Additionally, a few commenters stated that unit burden estimates per activity and/or respondent are too low, including: cost per industry submission, time needed for data gathering, time needed for due diligence, and rule familiarization (for processors).

Response: EPA agrees in part with these comments. After considering these comments, EPA adjusted the universe estimates and certain unit burden estimates. Regarding the number of chemicals and associated firms, EPA adds a group of chemicals termed "XU Chemicals" that was not included in estimates for the proposed rule. XU chemicals are defined in 40 CFR 711.6 and largely consist of polymers. This group of chemicals is listed on the Inventory, but is exempt from the reporting requirements of the CDR rule. Given that the CDR database is the primary source from which this rule's economic analysis draws measurements for counts of chemicals and firms, the XU Chemicals needed to be added. Regarding the number of processors, the origin for the proposed rule estimate of 161,550 processors was derived using the total chemical count for the initial reporting period combined with a model for "processors per chemical." The model is based on a previous analysis for a different proposed rule (and cited in this proposed rule's Burden and Cost Report.) For the final rule, the model is updated using the more current CDR 2016 data; detailed methodology is provided in Table 2 footnote (Ref. 2). Due to the increased value of the model coupled with the higher chemical counts (discussed above), processors are estimated for the final rule at 283,993 firms

Regarding unit burden estimates, EPA developed estimates for typical scenarios during start up and ongoing reporting to use as the representative average and then apply universe estimates to yield total burden estimates. Individual respondents may experience lower or higher

levels of burden. The activities of "time for data gathering," and "time needed for due diligence" are included in the unit burden estimate for compliance determination. Similarly, unit burden estimate for rule familiarization is based on the activities expected: "…becoming familiar with the full requirements of the rule, which includes reading the rule, understanding the various reporting and administrative requirements, and determining the manner in which reporting requirements will be met for each chemical substance" (Ref. 2). EPA also developed a range of burden hours estimates for processors' rule familiarization during start up at one to four hours, based on EPA judgment of how processors will familiarize themselves with the rule.

Changes to the Burden and Cost Estimates in the Final Rule: EPA revised the universe estimates to add XU Chemicals, and to incorporate a revised, larger estimate for the number of processor firms. EPA also revised the unit burden for processors' rule familiarization during start up.

Comment 16: One commenter indicated that EPA should justify why certification is required for non-CBI notices. Another commenter suggested the following changes to the proposed regulatory text for certification: 40 CFR 710.37(b)(3) should be corrected to "[a]n authorized official of a person" instead of "person," 40 CFR 710.29(d)(5) should be extended to substantiations as well as to claims and notices, and 40 CFR 710.37(b)(3) should be replicated in 40 CFR 710.37(a) so that it also applies to CBI claims for chemical identity in addition to other CBI claims.

Response: Certification statements are required under TSCA section 8(b)(9)(A) and are essential whenever information is submitted to the EPA. Certification statements are routinely required for data submitted to the EPA under TSCA as well as other statutes for both CBI and non-CBI submissions. Such statements ensure that the data the EPA ultimately relies on are valid and accurate. It also puts the submitter on notice of the consequences of submitting false,

inaccurate, or incomplete information to the Agency.

EPA agrees in large part with the comment recommending specific corrections to 40 CFR 710.37(b)(3) and 710.29(d)(5), the proposed regulatory provisions for certifications. EPA has revised the certification provisions in the rule, which currently appear at 40 CFR 710.37(e) (applicable to CBI claims and associated substantiations) and 710.29(d)(5) (applicable to all information reported on NOA Forms A and B). The rule clarifies that an "authorized official" submitting or substantiating any new or existing CBI claim must provide a certification, consistent with the requirements of TSCA section 14(c)(5).

While EPA does not agree with the commenter's implication that a request to maintain an existing CBI claim for specific chemical identity is subject to all of the same requirements and procedures that would apply to the assertion of a new claim under TSCA section 14(c), EPA finds it appropriate under the circumstances to require a certification statement for such requests that is consistent with TSCA section 14(c)(5), in addition to meeting the certification requirement of TSCA section 8(b)(9)(A). The earlier assertion of the CBI claim for specific chemical identity may have predated current provisions under TSCA subsections 14(c)(5) and (c)(1)(B) pertaining to the certification of a specific statement required for the assertion of a CBI claim. EPA does not believe that Congress intended the Agency to review existing CBI claims for chemical identity under TSCA section 8(b) without having the benefit of this certified statement.

Changes to the Certification Statements in the Final Rule. EPA revised the certification statement applicable to CBI claims to substitute "authorized official" for "person," and to address substantiation of claims, consistent with TSCA sections 8(b)(9)(A) and 14(c)(5).

Comment 17: One commenter indicated that the CBI claims process should be better

defined, particularly with regard to substantiation. Two commenters stated that the substantiation questions should be reduced in scope.

Response: EPA has extensively re-written the substantiation questions from the proposal in a manner intended to more succinctly secure answers for the basis of the CBI assertions for each data element as well as the CBI concerns on the linkage of data elements.

Changes to Substantiation Questions in the Final Rule: EPA has rewritten the substantiation questions to more succinctly secure answers for the basis of the CBI assertions for each data elements as well as the CBI concerns on the linkage of data elements.

IV. References

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

1. 2017. EPA. TSCA Inventory Notification (Active-Inactive) Requirements; Proposed Rule. **Federal Register** (82 FR 4255, January 13, 2017) (FRL 9956-28).

2. 2017. EPA. Burden and Cost Report for the Final Rule: TSCA Inventory Notification Requirements (RIN 2070-AK24, June 19, 2017).

3. 2017. EPA. Notice of Activity Form A and Form B; Final.

4. 2009. EPA. Notice of Commencement Form; Final.

5. 2005. EPA. Cross-Media Electronic Reporting Rule (CROMERR); Final Rule. **Federal Register** (70 FR 59848, October 13, 2005) (FRL 7977-1).

6. 2013. EPA. Electronic Reporting Under the Toxic Substances Control Act; Final Rule. **Federal Register** (78 FR 72818, December 4, 2013) (FRL 9394-6).

7. 2017. EPA. Response to Comments to the Proposed Rule, TSCA Inventory Notification (Active-Inactive) Requirements; RIN 2070-AK24. Docket # EPA-HQ-OPPT-2016-0426.

8. 2016. EPA. TSCA Chemical Data Reporting Fact Sheet: Imported Articles. *https://www.epa.gov/sites/production/files/2015-12/documents/cdr_fact_sheet_imported_articles_-_final_dec2015.pdf.*

9. 2016. EPA. TSCA Chemical Data Reporting Fact Sheet: Reporting After Changes to Company Ownership or Legal Identity. *https://www.epa.gov/sites/production/files/2015-05/documents/cdr_fact_sheet_company_changes.pdf.*

10. 2016. EPA. Chemical Data Reporting Frequent Questions. *https://www.epa.gov/sites/production/files/2016-07/documents/cdr_fq_final_july_11_2016.pdf.*

11. 2017. EPA. Information Collection Request for the TSCA section 8(b) Reporting Requirements for TSCA Inventory Notifications (EPA ICR No. 2562.02).

12. 2017. EPA. Small Entity Analysis Report for the Final Rule: TSCA Inventory Notification Requirements (May 30, 2017).

V. Statutory and Executive Order Reviews

Additional information about these statutes and Executive Orders can be found at *http://www2.epa.gov/lawsregulations/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 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) (identified under EPA ICR No. 2565.01 (OMB Control No. 2070-[new]), that estimates the potential burden and costs associated with the paperwork requirements contained in this rule (Ref. 11). You can find a copy of the ICR in the docket for this rule, 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: 1,685.

Manufacturers: 5,322.

Processors: 283,993.

Frequency of response: Once and on occasion.

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

Manufacturers: 38,613 hours.

Processors: 937,347 hours.

Estimated cost:

Manufacturers: $3.09 million.

Processors: $75.8 million.

Start-up year CDX Registrations burden/cost.

Respondents' obligation to respond: Mandatory.

Estimated number of respondents:(169 registrations).

Frequency of response: Once and on occasion.

Estimated burden: 90 hours.

Estimated cost: $7,022.

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: 225 hours.

Total estimated cost: $17,779.

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). When OMB approves this ICR, the Agency will announce that approval in the **Federal Register** and publish a technical amendment to 40 CFR part 9 to display the OMB control number for the approved information collection activities contained in this final rule.

C. Regulatory Flexibility Act (RFA)

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 entities subject to the requirements of this action are manufacturers, and processors of chemical substances, *i.e.*, small businesses in NAICS 325: Chemical Manufacturing, and 324: Petroleum and Coal Products Manufacturing. The most burdensome conditions are incurred during the start-up year, when all manufacturers are expected to report, and all processors are expected to become familiar with the requirements, but only a small number of the processors will likely also report. EPA has prepared a detailed analysis to evaluate the potential impacts quantitatively, a copy of which is available in the docket (Ref. 12).

The quantitative analysis addresses the "most affected" subset of entities who are expected to incur the highest potential burden under the rule (18 hours and $1,188 per firm) are the small entities manufacturing (or importing) chemicals that must submit NOAs involving an average of eighteen chemicals per entity in the start-up year. Although all processors are assumed to experience burden from becoming familiar with the requirements, only a small subset are expected to experience the burdens associated with submitting the NOAs.

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 as specified in Executive Order 13132 (64 FR 43255, August 10, 1999), because it does 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.

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

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

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.

K. Congressional Review Act (CRA)

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

List of Subjects in 40 CFR Part 710

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

Dated: June 22, 2017.

E. Scott Pruitt,

Administrator.

Therefore, 40 CFR Chapter I is amended as follows:

PART 710— COMPILATION OF THE TSCA CHEMICAL SUBSTANCE INVENTORY

1. Revise the authority citation for part 710 to read as follows:

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

2. Revise § 710.1 through § 710.4 as subpart A and add a new subpart B, to read as follows:

Subpart A—General Provisions

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.

3. 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 (Inventory) and the designation of chemical substances on the TSCA Inventory as active or inactive in U.S. commerce.

* * * * *

4. 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 (TSCA), 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 nonexempt 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.

5. 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 chemical substance that was added to the Inventory on or after June 21, 2006 pursuant to a Notice of Commencement under 40 CFR 720.102 received by the Agency on or after June 21, 2006, and any chemical substance subject to commercial activity designation that the Administrator designates 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 is not an interim active substance, it was added to the Inventory before June 21, 2006, 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 for protection of the specific chemical identity of a chemical substance that is listed on the confidential portion of the Inventory, asserted prior to June 22, 2016.

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, effective 90 days after the Administrator identifies the chemical substance for such designation.

Interim active substance means any chemical substance that was reported, pursuant to 40 CFR part 711, as having been manufactured in and of the calendar years: 2010, 2011, 2012, 2013, 2014, or 2015.

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.

Notice of Activity Form A means the form for supplying retrospective notification under TSCA section 8(b)(4), for which the submission obligation is described in 40 CFR 710.25(a).

Notice of Activity Form B means the form for supplying forward-looking reporting under TSCA section 8(b)(5), for which the submission obligation is described in 40 CFR 710.25(c).

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

Possession or Control means in the possession or control of any person, or of any subsidiary, partnership in which the person is a general partner, parent company, or any company or partnership which the parent company owns or controls, if the subsidiary, parent company, or other company or partnership is associated with the person in the research, development, test marketing, or commercial marketing of the chemical substance in question. Information is in the possession or control of a person if it is: (1) In the person's own files including files maintained by employees of the person in the course of their employment. (2) In commercially available data bases to which the person has purchased access. (3) Maintained in the files in the course of employment by other agents of the person who are associated with research, development, test marketing, or commercial marketing of the chemical substance in question.

Reportable chemical substance means a chemical substance that is listed on the 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) a chemical substance that was added to the confidential portion of the Inventory before June 22, 2016, 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 (including imported) a chemical substance subject to commercial activity designation 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(a), unless such person has evidence in the form of a CDX receipt, documenting EPA's receipt of a Notice of Activity Form A from another person, for the same chemical substance, or unless the prior manufacturing of such a substance is not known to or reasonably ascertainable by the person. Evidence in the form of a CDX receipt for a Notice of Activity Form A is not a basis for exemption from the requirements of § 710.25(c) if the chemical substance is ultimately designated as inactive due to withdrawal of the Notice of Activity Form A.

(b) *Who else may submit the Notice of Activity Form A?* Any person not required to submit a Notice of Activity Form A under § 710.25(a), who manufactured (including imported) or processed a reportable chemical substance, at any time during the lookback period, may submit a Notice of Activity Form A as specified under § 710.29 and § 710.30(a).

(c) *Who must submit the Notice of Activity Form B?* Any person who intends to manufacture (including import) or process an inactive 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(b), unless the presence of the inactive substance on the confidential portion of the Inventory is not known to or reasonably ascertainable by the person.

§ 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 in small quantities solely for research and development.

(2) The import or processing 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).

(4) The manufacturing or processing of a chemical substance solely for export from the United States as described in § 720.30(e) or § 721.3, except where the Administrator has made a finding described in TSCA section 12(a)(2).

(5) The manufacturing or processing of a chemical substance solely for test marketing purposes.

(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.* A person who reports information to EPA under this subpart 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 notice for each chemical substance that the person is required to report. Using e-NOA and CISS and registering in CDX are described in instructions available from EPA at the Web sites set forth in § 710.39.

(b) *Information to be reported on the Notice of Activity Form A.* A person submitting a Notice of Activity Form A under § 710.25(a) or § 710.25(b) must submit the information specified in § 710.29(d) for each reportable chemical substance. 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.

(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 substance intended to be manufactured or processed.

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

(2) The anticipated date by which the inactive substance is to be manufactured or processed in the United States. If the Notice of Activity Form B is filed prior to the effective date of the chemical substance’s inactive designation, the most recent date of manufacturing or processing may be provided in lieu of an anticipated date.

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

(1) *Company.* The name and address 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 system described under § 710.29(a) will provide a list of reportable chemical substances from which a person can select his or her chemical. The list will include the correct CASRN and CA Index name used to list a non-confidential chemical substance on the Inventory. For confidential substances on the Inventory, the list will include the 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 refer the supplier to EPA's 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.

(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 refer the supplier to EPA's 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) Joint submissions must be submitted electronically using e-NOA, CISS, and CDX (see § 710.39).

(5) *Certification statements.* The authorized official must certify that the submitted information has been completed in compliance with the requirements of this part as described in this paragraph.

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

(ii) The following is required certification language for an authorized official submitting a Notice of Activity Form A under § 710.25(a) or § 710.25(b): "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 also certify that I have manufactured, imported, or processed the above chemical between the dates of June 21, 2006 and June 21, 2016. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for

such unlawful conduct, including the possibility of fine and imprisonment."

(iii) The following is required certification language for an authorized official submitting a Notice of Activity Form B under § 710.25(c): "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 also certify that I have intent to manufacture, import, or process the above chemical within 90 days of submission. I am aware it is unlawful to knowingly submit incomplete, false and/or misleading information, and there are significant criminal penalties for such unlawful conduct, including the possibility of fine and imprisonment."

§ 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) and § 710.25(b) 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 [420 days after the date on which the final rule is published in the **Federal Register**].

(3) *Withdrawal of a Notice of Activity Form A.* A Notice of Activity Form A submitted under § 710.30(a)(1) or § 710.30(a)(2) may be withdrawn by the submitter not later than [420 days after the date on which the final rule is published in the **Federal Register**]. If EPA receives a timely request to withdraw a previously submitted Notice of Activity Form A for a chemical

substance subject to commercial activity designation, and EPA has not received a Notice of Activity Form A from another submitter for the same chemical substance, EPA will not designate the chemical substance as active. A Form A withdrawn under this paragraph will not satisfy the obligation under this rule to submit a Form A.

(b) *When must a Notice of Activity Form B be submitted?* (1) *Manufacturers and processors*. 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 90 days prior to the anticipated date of manufacturing or processing.

(2) *When else may a Notice of Activity Form B be submitted?* A Notice of Activity Form B that will later be required to be submitted under § 710.25(c) may be submitted during the 90-day period between EPA's identification of a chemical substance for inactive designation and the effective date for such designation, by a person who is currently manufacturing or processing such chemical substance or who anticipates manufacturing or processing such chemical substance within 90 days following submission.

(3) *When may EPA execute a request to withdraw a Notice of Activity Form B?* If EPA receives a request to withdraw a previously submitted Notice of Activity Form B from the submitter of the Notice of Activity Form B and EPA has neither yet moved the subject chemical substance from the inactive to the active Inventory nor yet moved the subject chemical substance from the confidential portion of the Inventory to the public portion of the Inventory as a result of the original submission, then EPA may execute the request.

§ 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.* A person submitting information under this part may request to maintain an existing claim of confidentiality for the specific chemical identity of a reportable chemical substance, but may do so only if the identity of the chemical substance is listed on the confidential portion of the Inventory as of the time the notice is submitted for that chemical substance under this part. A request 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 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, subpart B.

(1) *Notice of Activity Form A.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity may submit with the notice answers to the questions in paragraphs (c)(1) and(c)(2) of this section, signed and dated by an authorized official. If these answers are submitted less than five years before the date on which substantiation is due pursuant to TSCA section 8(b)(4)(D)(i), the 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 TSCA section (8)(b)(4)(D)(i). Answers that do not include the answers to all applicable questions in paragraph (c) of this section will not be deemed to be substantiations made under the TSCA section (8)(b)(4)(D)(i) requirement.

(2) *Notice of Activity Form B.* A person requesting to maintain an existing claim of confidentiality for specific chemical identity must submit answers to the questions in paragraphs (c)(1) and (c)(2) 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 confidentiality claim as deficient, so that the specific chemical identity is not subject to a confidentiality claim, and may make the information public without further notice.

(b) *Information other than specific chemical identity.* A person submitting information under this part may assert a claim of confidentiality for information other than specific chemical identity. Any such confidentiality claim must be made at the time the information is submitted. 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, subpart B. A person asserting a claim of confidentiality under this subsection must submit with the notice answers to the questions in paragraph (c)(1) of this section, signed and dated by an authorized official. If no claim is asserted at the time the information is submitted, or if the answers to the questions in paragraph (c)(1) of this section are not provided, EPA will consider the information as not subject to a confidentiality claim and may make the information public without further notice.

(c) *Substantiation questions.* Persons asserting that information is exempt from substantiation pursuant to TSCA section 14(c)(2) must answer only the question in paragraph (c)(1)(i) of this section.

(1) *Substantiation questions for any confidentiality claim.* For any information with a confidentiality claim that you assert is exempt from substantiation pursuant to TSCA section 14(c)(2), answer only the question in subparagraph (i) of this paragraph. For all other information with a confidentiality claim, answer the questions in subparagraphs (ii) – (vi) of this paragraph. If more than one data element on Form A or Form B is claimed as confidential, you must answer the applicable questions individually for each data element. If the answer to a question applies for all confidentiality claims on the form, indicate this in your substantiation response.

(i) Do you believe that the information is exempt from substantiation pursuant to TSCA section 14(c)(2)? If you answered yes, you must individually identify the specific information

claimed as confidential and specify the applicable exemption(s)

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

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

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

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

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

(2) *Substantiation for confidentiality claims for chemical identity.* Is the confidential chemical substance publicly known to have ever been offered for commercial distribution in the

United States? If you answered yes, explain why the information should be treated as confidential.

(d) *Confidentiality of substantiation.* If any of the information contained in the answers to the questions listed in paragraph (c)(1) or (c)(2) of this section is claimed as confidential business information, the submitter must clearly indicate such by marking the substantiation as confidential business information as provided in a Notice of Activity Form A or Form B.

(e) *Certification statement for claims.* An authorized official of a person submitting or substantiating a claim of confidentiality or a request to maintain an existing claim of confidentiality for specific chemical identity must certify that the submission complies with the requirements of this part by signing and dating the following certification statement: "I certify that all claims for confidentiality made or sought to be maintained with this submission are true and correct, and all information submitted herein to substantiate such claims is true and correct. I further certify that it is true and correct that:

(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 my company; and

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

Any knowing and willful misrepresentation is subject to criminal penalty pursuant to 18 U.S.C. § 1001."

§ 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) *Web site.* 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) *Email.* Email the EPA CDX Help Desk at *HelpDesk@epacdx.net*.

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

(1) *Web site.* Go to the EPA New Chemicals under the Toxic Substances Control Act Web site at *https://www.epa.gov/reviewing-new-chemicalsunder-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) *Email.* Email the EPA TSCA Hotline at *TSCA-Hotline@epa.gov*.