Reference 7 –

Response to Comments to the Proposed Rule, TSCA Inventory Notification (Active-Inactive) Requirements

June 22, 2017

Docket # EPA-HQ-OPPT-2016-0426

RIN 2070-AK24

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 TSCA itself) 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 document will do so expressly.

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 ten-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: One commenter stated that naturally occurring substances should not be required to be reported.

Response: EPA indeed proposed to exclude naturally occurring substances from reporting, provided that the manufacturing and processing of such substances meet the criteria set forth in 40 CFR 710.27(b). No regulatory change is needed. Naturally occurring substances are considered to be automatically included on the Inventory as the category "Naturally Occurring Chemical Substances" (42 FR 64578). The whole category of Naturally Occurring Chemical Substances, therefore, is designated as active substances by this action and not subject to reporting.

Comment 4: One commenter stated that TSCA does not provide a basis for exempting chemical substances from the rule merely based on their presence on the interim active list. The commenter further stated that EPA should limit the CDR-based reporting exemption to those companies that reported substances under CDR. The commenter also stated that results from the 2012 CDR are not an appropriate basis for exemption, and that any CDR-based reporting exemption should be limited to the 2016 CDR. The commenter expressed concern that some of the persons who were manufacturing a chemical substance in 2011 or 2012 may no longer be manufacturing that chemical substance, leading to a "false positive" active designation. The commenter also expressed concern that use of 2012 CDR data will result in CBI claims for data elements reported on the 2012 CDR (other than chemical identity) not being re-examined by EPA under TSCA's updated confidentiality provisions.

Response: TSCA sections 8(b)(4)(A)(i) and 8(a)(5) provide a legal basis for EPA to exempt from reporting requirements those chemical substances that appear on the interim active list. While TSCA section 8(b)(6) indicates that the primary purpose of the interim active list is prioritization under TSCA section 6(b), TSCA section 8(b)(4)(A)(i) incorporates by reference the language of section 8(a)(5)(A), which makes clear that EPA must, to the extent feasible, "not require reporting which is unnecessary or duplicative." The statutory objective that motivates the collection of information on whether particular persons manufactured or processed a chemical substance during the lookback period is to distinguish active substances (those that were manufactured or processed during the lookback period) from inactive substances (those that were not manufactured or processed during the lookback period). A chemical substance on the interim active list has clearly been manufactured during the lookback period and it would therefore be inconsistent with TSCA section 8(a)(5)(A) to require further notification regarding that substance under TSCA section 8(b)(4). Moreover, 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 define the notice that must be submitted in such a way as to exclude prior reporting submitted under CDR from constituting such a notice. Had Congress intended to preclude the Administrator from adopting reporting exemptions for manufacturers of substances appearing on the interim active list, Congress could have done so by specifying that the Administrator shall require manufacturers to submit a *new* notice for each chemical manufactured during the lookback period.

EPA also disagrees that CDR-based reporting exemptions should be limited to those companies that reported substances under CDR. The statutory objective of the retrospective

notification process is not to confirm (from the absence of notification from a particular manufacturer or processor) that a specific manufacturer or processor is or is not manufacturing or processing the chemical substance. See TSCA section 8(b)(4)(A)(iii) (EPA to designate *chemical substances* as inactive based on non-reporting, not to designate particular manufacturers or processors as inactive). Updating information on how many persons are continuing to manufacture a particular substance, and at what production volumes, is covered under a separate rule, the CDR rule, under TSCA section 8(a). The language of section 8(b)(4)(A)(i) provides only 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 limit a CDR-based reporting exemption to those companies that reported substances under CDR, 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.

EPA further disagrees that its inclusion in the interim active list of chemical substances reported under 2012 CDR, and the Agency's adoption of a reporting exemption for such substances, will generate "false positives" for active substances. A chemical substance that was manufactured in 2011 (and accordingly reported under the 2012 CDR), but has not since been manufactured, is correctly classified as an active substance under the statutory framework. Section 8(b)(4)(A)(i) refers to notification for chemical substances manufactured "during the 10-year period" ending on the day before June 22, 2016; it does not limit such reporting to only those substances that were still being manufactured during the 2016 CDR cycle. Even if EPA had not designated substances as active based on 2012 CDR reporting, a person who

manufactured a chemical substance for nonexempt commercial purpose in 2011, and subsequently ceased manufacturing that substance, would have been required to submit a retrospective notice under section 8(b)(4)(A)(i), and EPA would then have been required to list that substance as active under section 8(b)(4)(A)(ii). Finally, EPA disagrees with the commenter that the statutory objectives for this rule include requiring CBI claims unrelated to chemical identity and asserted in 2012 CDR submissions to be reasserted under the new requirements of the Lautenberg Act. The commenter does not explain its basis to believe that this was one of the intended purposes of the rule.

Comment 5: 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 an NOA 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 6: 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 five 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 five-year substantiation requirement, while NOCs submitted earlier in the 10-year lookback period for retrospective reporting may not satisfy the five-year substantiation requirement. Note that a voluntary substantiation submitted with an NOA Form A might also not satisfy the five-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 7: Several commenters stated that substances that are not currently in commerce should not be required to be reported, nor should they be made active, even though the substances were manufactured during the ten-year retrospective reporting period. One commenter elaborated that companies that may have manufactured or imported substances during the ten-year reporting period, but that have since divested such businesses and that may not have intent to manufacture or import such substances in the future, should not be obliged to report such substances.

Response: EPA disagrees with this comment. The statute indicates that the substantive criterion for whether a chemical substance is active or inactive is whether that chemical substance was manufactured or processed during the "10-year period ending on [June 21, 2016]." See TSCA section 8(b)(4)(A)(i). Thus, EPA does not believe that the purpose of the information collection would be served by limiting it to identifying chemical substances for which there is a contemporary intent to continue manufacturing or processing in 2017. The retrospective reporting obligation, therefore, is based on whether a substance was manufactured or processed within the last ten years, not on whether the manufacturer currently intends to continue distributing in commerce or whether recipients of the products are currently intending to continue distributing the substance in commerce.

Comment 8: 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 9: 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 NOA Form A exemption, and the NOA 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 10: One commenter recommended that the retrospective submission period should remain open after the proposed submission deadlines, stating that keeping the submission period open (e.g., for up to a total of two years, until after the first Inventory is published) will allow for due diligence. Two commenters indicated that the retrospective submission period for manufacturers and importers should be extended beyond the first 180-day reporting period into the processor reporting period. A few commenters similarly requested that the retrospective

submission period for importers making joint submissions should be extended to 360 days (same as for processors). A few commenters indicated that processors should be allowed to report during the first 180-day submission period for manufacturers, and that manufacturers and importers should be able to report chemicals that they process during either the first 180-day submission period for manufacturers or the subsequent 180-day submission period for processors.

Response: EPA disagrees with comments to keep the retrospective submission period open after deadlines or to extend the submission period for domestic manufacturers or importers beyond the 180-day submission period. Import is manufacturing under TSCA. See TSCA Section 3(9). Thus, the 180-day statutory deadline for manufacturer reporting applies with equal force to importers and domestic manufacturers. Joint submissions from importers are subject to the same statutory timing constraints as any other submissions from manufacturers. EPA agrees with comments that processors can report during any part of their voluntary submission period, including the part of their voluntary submission period that runs concurrent with the mandatory submission period for manufacturers. This is consistent with both the proposed and final wording of 40 CFR 720.30(a)(2). The analysis is the same for joint submissions from processors.

Comment 11: 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 12: 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 13: One commenter stated that processors should be allowed to submit NOA Form B voluntarily. A second commenter suggested that it should be made clear that only one NOA Form B notice is required for re-designating a substance as active. The commenter elaborated that, if domestic manufacture or import is anticipated to occur, it should not be necessary to provide a date for subsequent processing, and similarly, if a processor submits an NOA Form B for anticipated processing of an inactive substance, the processor is not required to determine the date in the past when the substance had been manufactured or imported by another party.

Response: EPA disagrees with the comment to allow processors to voluntarily submit an NOA Form B. Unlike retrospective provisions under TSCA, in which EPA "may require processors" to report (TSCA section 8(b)(4)(A)(i)), forward-looking provisions under TSCA specifically require persons that intend to "manufacture *or process*" an inactive substance for nonexempt commercial purpose to notify EPA before the date on which the inactive substance is "manufactured *or processed*." TSCA section 8(b)(5)(B)(i) (emphasis added). Therefore, a processor that intends to process an inactive substance for nonexempt commercial purpose is required to notify EPA before the date on which the inactive substance is processed and in a manner specified by this rule.

EPA agrees with the comment that only one NOA Form B is required for re-designating a substance as active. TSCA states that, on receiving a forward-looking notice, EPA shall designate the applicable chemical substance as an active substance. See TSCA section 8(b)(5)(B)(iii). Therefore, upon receipt of the first NOA Form B for a particular inactive substance, EPA will re-designate the substance as active, and the substance will no longer be subject to forward-looking reporting. For example, if manufacturing of an inactive substance is intended, the manufacturer is required to submit an NOA Form B for the manufacturing activity prior to the date that manufacturing occurs. The submitter is not required to also provide a date for processing that is anticipated to occur subsequent to manufacturing, nor is a separate NOA Form B required for the processing activity, because the substance will be re-designated as active as a result of the NOA Form B submitted for the manufacturing activity.

Comment 14: A few commenters stated that there should be no waiting period or Agency approval required following submission of an NOA Form B prior to commencement of manufacture or import of a formerly "inactive" substance.

Response: TSCA section 8(b)(5)(B)(i) states that "[a]ny person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed." The plain meaning of this text is that the manufacture or processing of an inactive substance would be unlawful if the manufacturer or processor has not submitted an NOA Form B to EPA on a prior day. Thus, the "waiting period" after submitting a valid NOA Form B (i.e., one submitted consistent with the requirements of this rule) is directly controlled by the statute, it is not contingent on EPA authorization, and it could not exceed 24 hours. TSCA directs EPA to re-designate the substance as active "on receiving" an NOA Form B. See TSCA section 8(b)(5)(B)(iii). The re-designation of a chemical substance as active does not involve a substantive review of the chemical substance. Finally, with respect to a CBI substance for which the submitter wishes to maintain an existing CBI claim for chemical identity, TSCA section 8(b)(5)(B)(ii)(II) establishes a subsequent requirement that the submitter must supply substantiation of the claim within 30 days. Failure to timely substantiate the CBI claim for chemical identity would be a deficiency in that claim, but it would not retroactively invalidate the NOA Form B, such that manufacture or processing would become unlawful.

Comment 15: *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 16: 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 17: 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 18: Several commenters stated that the scope of the rule should be expanded in order to gather additional data from submitters, such as sites of manufacture, importation, or processing, production volumes, storage locations, or known uses.

Response: EPA disagrees with this comment. The reporting required by this rule is intended to support two statutory objectives in a straightforward manner: First, to enable EPA to designate substances on the TSCA Inventory as active or inactive. (Designation is based on whether or not the chemical substance was manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on June 21, 2016, with inactive substances subject to becoming

active based on later-submitted intent to manufacture or process. See TSCA section 8(b)(4)(A)(i) and 8(b)(5)(B).) Second, to require that persons seeking to maintain an existing claim for protection against disclosure of the specific chemical identity of a substance on the confidential portion of the Inventory submit a notice that includes such request. See TSCA section 8(b)(4)(B)(ii). Additional data elements, beyond those proposed, are unnecessary to accomplish these statutory objectives. Furthermore, EPA does not believe that reporting under TSCA section 8(b) was intended to duplicate the broader data-collection purposes of Chemical Data Reporting under TSCA section 8(a). See TSCA section 8(b)(4)(A)(i), specifically admonishing EPA to ensure that this rule is consistent with the TSCA section 8(a)(5)(A) general requirement that the Agency avoid, to the extent feasible, TSCA section 8 reporting that is unnecessary or duplicative. Increasing the scope or frequency of information collection under the general information collection authorities of TSCA section 8(a) is beyond the scope of this section 8(b) rulemaking.

Comment 19: 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 NOA 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 who intends to manufacture or process a chemical substance under a PMN exemption 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 does not believe that a person who intends to manufacture or process an inactive confidential chemical substance under a PMN exemption, but who does not know and cannot reasonably ascertain that the substance is inactive, should be viewed as intending to manufacture an inactive substance within the meaning of TSCA section 8(b)(5). In this regard, EPA notes a distinction between the wording of section 5(a) – which flatly bars the manufacture of a new chemical substance without notice – and section 8(b)(5) – which is drafted in terms of the intent to manufacture an inactive substance. EPA also believes that Congress did not intend for section 8(b)(5) notification to pose a significant bar to manufacture or processing of a chemical substance, or to require a delay in such manufacture or processing. In this regard, EPA notes that Congress clearly intended that inactive substances remain on the Inventory and therefore not require section 5 notice or review. EPA also believes that Congress intended that a person be able to commence manufacture or processing of a chemical substance without delay following submission of an 8(b)(5) notice. In this context, EPA believes it would be inconsistent with the structure and purpose of section 8(b) to interpret the statute such that a manufacturer or processor of a confidential chemical substance under a PMN exemption would be required to undergo a lengthy process – akin to the bona fide process under TSCA section 5 – to first determine whether their chemical substance is a confidential inactive Inventory substance prior to being able to manufacture or process the substance. 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. A person submitting an NOA Form B for a chemical substance must know the identity of the chemical substance. 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 20: 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 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.

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 21: Two commenters stated that EPA should allow for Inventory corrections without privity.

Response: EPA disagrees with the comment that this rulemaking should address broader EPA practices regarding the acceptance of Inventory corrections. EPA published correction guidelines for substances reported to the initial TSCA Inventory in the **Federal Register** issue of July 29, 1980 (45 FR 50544). These guidelines reflect EPA's current and longstanding practice of only accepting correction requests that are limited in scope and made by the submitter of the original TSCA Inventory notice or its legal successor. EPA's proposal did not include the establishment of rules to govern these practices. Addressing arguments that EPA's practices should change is beyond the scope of this rulemaking.

Comment 22: 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 23: A few commenters stated that electronic reporting should be optional for processors.

Response: EPA disagrees with the comment. EPA has committed to cost effective reporting approaches that benefit both industry and the government. Accordingly, changes to e-reporting for TSCA programs have streamlined and reduced the administrative costs and burdens of TSCA-based reporting requirements overall. Electronic submission of data in electronic notice templates have been shown to significantly reduce errors, given problems associated with paper submissions (e.g., chemical identity errors). As explained in both the proposed and final rule preamble (Unit II.D), EPA in general, and the TSCA program overall, has implemented an e-reporting initiative, and that applies across TSCA program reporting requirements. Therefore, this new reporting requirement is also implemented on the basis of 100% e-reporting. On balance, EPA believes that the efficiencies provided by electronic reporting justify the burden associated with requiring processors to use this method instead of paper submissions.

EPA understands that processors may be less familiar with electronic reporting via CDX, but EPA has evaluated that cost to be of a minimal impact (see details in Burden and Cost Report and Small Entity Analysis Report for the final rule).

Comment 24: A few commenters requested clarification that reporting is allowed at either a corporate or site level, whichever is most appropriate for the reporting company.

Response: EPA confirms that level of reporting within a company can be at the corporate or site level, whichever is appropriate for the reporting company.

Comment 25: Several commenters suggested that NOA Form A's should be allowed to be submitted in batch. Some commenters elaborated that EPA should offer XML functionality or a spreadsheet template for uploading batch data.

Response: EPA agrees that allowing for batch submissions in the electronic reporting system would make reporting more convenient for submitters, and EPA has endeavored to do so to the extent practicable. EPA was able to develop functionality in the electronic reporting system whereby companies will be able to submit multiple chemical substances in one CDX session in a manner that the substances will be transmitted as individual reports. Companies will be able to upload batch data in a Microsoft Excel spreadsheet. EPA is not enabling XML functionality for batch commercial activity reporting due to errors that occurred with such functionality offered for 2016 CDR and the inability to address such errors, such that the functionality would be reliable to submitters for commercial activity reporting, by the statutory deadline to finalize this rule.

Comment 26: *A few commenters suggested that chemical substance identities should be entered onto reporting forms using CAS Registry Numbers as the primary identifier, without also having to enter chemical names or structures.*

Response: EPA agrees in part with this comment. Reporting chemical identities under TSCA typically involves the primary identifiers used to list chemical substances on the TSCA Inventory, which are CASRN and CA Index names for non-CBI substances and these same

identifiers or Accession Numbers and generic names for CBI substances. However, because the electronic reporting system will include a pick list comprised of each chemical substance subject to reporting, submitters will not have to enter chemical identity information for a reportable chemical substance, but rather will select the substance from the pick list. The pick list will not include CBI, so non-CBI substances will be listed by CASRNs and CA Index names, and CBI substances will be listed by EPA accession numbers and generic names. Submitters can search for substances on the pick list using any of the primary identifiers.

Comment 27: Several commenters stated that EPA should provide more information about use of CDX for reporting as well as guidance and training.

Response: This rule will require persons submitting notices of activity to use CDX, EPA's electronic reporting portal, and the Chemical Information Submission System (CISS), EPA's web reporting tool. Both CDX and CISS are currently used for other reporting under TSCA, including for submitting data under TSCA sections 4, 5, 8(a), and 8(d). EPA will be providing detailed guidance within the system that will include specific instructions for submitting notices electronically under this rule. Assistance will also be available through the EPA CDX Help Desk and the EPA TSCA Hotline. Additionally, EPA plans to offer webinars specific to the use of CDX and CISS for reporting under this rule.

Comment 28: A few commenters suggested that existing TSCA Inventory nomenclature should be maintained and existing TSCA Inventory definitions should not be redefined.

Response: This rule does not alter TSCA Inventory nomenclature and listings. Reporting is based on existing substances on the Inventory which are identified by and listed using existing nomenclature conventions.

Comment 29: Two commenters stated that nomenclature "alerts" should be allowed to be

voluntarily submitted during the notification process, including alerts to EPA concerning substances that may warrant a nomenclature equivalency determination at a future date. A few additional commenters stated that guidance or other means to address nomenclature equivalency should be finalized separately or as part of the rule. One commenter elaborated that EPA should commit dedicated resources to respond to questions concerning nomenclature interpretation and assist in resolving other nomenclature issues.

Response: Persons can submit questions and provide voluntary information on nomenclature and other related information to EPA using existing mechanisms (e.g., Inventory Correspondence). It is not necessary to modify the rule to enable the submission of voluntary information or to enable persons to contact EPA on TSCA Inventory matters through correspondence. Developing and finalizing guidance on nomenclature equivalency is furthermore beyond the scope of the rule. If a submitter believes that a substance that it manufactured or processed is listed on the Inventory using more than one name and CAS Registry Number, the submitter should report their substances using the listing that represented the reportable commercial activity in which it was engaged.

Comment 30: Two commenters indicated that EPA should clarify how the "two-percent rule" for polymers operates in this context of this rule. Three commenters also indicated that EPA should incorporate the Agency's policy on free radical initiators in this rule or clarify how this policy is incorporated in the rule.

Response: EPA intends to follow its existing "two-percent rule" and free radical initiator policies for polymers in this rule. Polymeric substances listed on the TSCA Inventory are subject to retrospective reporting under this rule if they were manufactured during the ten-year reporting period for nonexempt commercial purpose. A company could have manufactured an Inventory-

listed polymer using additional monomer reactant(s), and the manufactured polymer would be covered by the existing listing, *if* the additional monomer reactant(s)were used at two weight percent or less and not identified to be included in the polymer description on the Inventory. See 40 CFR 720.45(A)(2)(iii). Similarly, a company could have manufactured an Inventory-listed polymer using a free-radical initiator, and the manufactured polymer would be covered by the existing listing, *if* the free-radical initiator was used at less than or equal to two weight percent and not identified to be included in the polymer description on the Inventory. See *https://www.epa.gov/sites/production/files/2015-05/documents/polymers.pdf*. In such case the company would report under this rule using the existing polymer listing. If, however, a company manufactured a polymer using additional monomer reactant(s) and/or a free-radical initiator at greater than two weight percent, then the chemical identity of the manufactured polymer would be required to include the additional monomer reactant(s) and/or a free-radical initiator and, therefore, would be considered to be a different polymeric substance for the purposes of TSCA. If the different polymeric substance is also listed on the Inventory, then the company must report under this rule using the other listing.

Comment 31: 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 32: A few commenters disagreed with the proposed requirement that manufacturers and processors retain records for five years, stating that record retention is an unnecessary burden that is not required by statute. Two commenters requested clarification that the requirement does not apply to processors.

Response: EPA disagrees with the comment that record retention is not required by statute. TSCA section 8(b)(9)(B) provides that "manufacturers and processors, as applicable, shall be required . . . to retain a record documenting compliance with the rule and supporting confidentiality claims for a period of 5 years beginning on the last day of the submission period." EPA provided in the proposed rule that records relevant to retrospective notification must be retained by manufacturers and processors, as applicable, for a period of 5 years beginning on the last day of the submission period, as required by TSCA section 8(b)(9)(B) for rules promulgated under subsection 8(b). EPA also proposed that records relevant to forward-looking notification must be retained for a period of 5 years beginning on the day that the notice was submitted. In the context of forward-looking reporting, EPA interprets "the last day of the submission period" in TSCA section 8(b)(9)(B) to refer to the date of submission of the notice. EPA finalized these recordkeeping provisions in this rule. See 40 CFR 710.35.

In response to the request for clarification regarding record retention requirements for processors, if a processor has chosen to submit a retrospective notification (NOA Form A), the processor is "subject to the notification requirements of this part" pursuant to 40 CFR 710.35, and must retain records relevant to that notification for a period of 5 years beginning on the last day of the retrospective submission period for processors. Such records would "document[] compliance with the rule" as provided in TSCA section 8(b)(9)(B) by documenting the information reported to EPA in NOA Form A. The recordkeeping requirements for retrospective reporting are inapplicable to processors who choose not to submit an NOA Form A. Any processor who submits a forward-looking notification (NOA Form B) is subject to the recordkeeping requirements.

Comment 33: 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 34: A few commenters stated that EPA should exercise enforcement flexibility and discretion for notices submitted with errors or for failure to report by the required deadline

because a chemical substance or commercial activity was missed. Two commenters requested that enforcement provisions be incorporated in the rule to distinguish between 40 CFR 710.25(c) and 40 CFR 707.20, regarding potential enforcement action and penalties, when an NOA Form B is not submitted when required.

Response: It is a violation of TSCA to fail to report information by stated deadlines as required by this rule and TSCA. Regarding importation, commercial importation activity is subject to 40 CRR 710.25(c) Notice of Activation requirements. Customs and Border Protection regulations require importers to certify at the time of import only for compliances with TSCA sections 5, 6, and 7 (see 19 CFR 12.122(b)). However, imports must also be in compliance with certain other sections of TSCA under 19 CFR 12.122(b), which instructs the director of the port to detain shipments whenever the port director has reasonable grounds to believe that the shipment is not in compliance with TSCA. By not submitting a timely NOA Form B for an imported inactive substance, an importer is not complying with TSCA. Therefore, EPA would consider whether to request that Customs refuse entry under TSCA §13(a)(1)(a) for a substance that fails to comply with any rule under TSCA.

Comment 35: *One commenter stated that section 8 reporting requirements are not intended to place conditions on the right to operate, which accompanies the Inventory status of a substance.*

Response: TSCA section 8(b)(5)(B)(i) requires that "[a]ny person that intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance shall notify the Administrator before the date on which the inactive substance is manufactured or processed." Thus, by statute, companies are not authorized to manufacture (including import) or process an inactive chemical substance unless an NOA Form B is submitted. Manufacturing or processing a chemical substance on or after the effective date of an

inactive designation for that substance, without first sending in an NOA Form B, is unlawful.

Comment 36: A few commenters stated that the Agency must protect confidentiality and should develop an infrastructure that protects this data.

Response: EPA has a responsibility to protect confidential data. See generally TSCA section 14. EPA has an established infrastructure to protect confidential data that includes procedures for receiving, tracking, handling, and storing such data. Confidential information submitted under this rule will be protected according to this existing infrastructure. The Agency will only release such information in accordance with applicable law and regulations.

Comment 37: One commenter stated that EPA should make clear that confidentiality claims may only be asserted for substances that are already confidential on the Inventory.

Response: The proposed rule at 40 CFR 710.37(a) states that persons may request to maintain an existing claim of confidentiality for specific chemical identity "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. EPA finalized this language in the rule without change. Consistent with TSCA section 8(b)(8), new claims of confidentiality cannot be asserted for chemical substances that are already on the public portion of the Inventory and therefore known to be in U.S. commerce as a chemical substance with TSCA Inventory status.

Comment 38: Several commenters expressed support for EPA's proposal to allow CBI claims to be maintained by persons other than the original claimant. One commenter disagreed with the proposed rule, stating that EPA should not allow a company to request to maintain a CBI claim for chemical identity unless it can demonstrate it previously asserted that claim.

Response: EPA does not agree with the latter commenter that a company that has benefited or otherwise relied on an existing claim of confidentiality for specific chemical identity, that may or

may not have previously filed a TSCA notice, should be prohibited from asserting a claim of confidentiality for specific chemical identity in an NOA Form A or B. EPA is finalizing its proposal to permit any manufacturer or processor submitting a Notice of Activity under TSCA section 8(b)(4)(A) to 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 TSCA 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, due to mergers, acquisitions, or other business events, 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). Moreover, the statutory requirements for substantiation and Agency review of chemical identity CBI claims are sufficient to ensure that chemical identities do not remain confidential on the basis of frivolous CBI claims.

Comment 39: 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.

Comment 40: One commenter stated that CBI claims for chemical identity in retrospective reports should be substantiated at the time reports are filed. Another commenter stated that this rule needs to clarify EPA's obligation to review "early" substantiation and require that early substantiation be updated if the claimant can reasonably ascertain that circumstances have changed.

Response: TSCA section 8(b)(4)(D) provides a framework for the development of a review plan and substantiation of the identities of active chemical substances claimed as CBI. This rule provides that submitters may choose to substantiate existing CBI claims for specific chemical identity at the time of filing of an NOA since they will be required to substantiate other data elements claimed as CBI at that time, or they may choose to substantiate CBI claims for chemical identity following the publication of the Review Plan. 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 five-year timeframe mandated by TSCA section 8(b)(4)(E).

EPA disagrees that it is necessary to revise the rule to require updates from submitters of early substantiation. The rule already makes clear that if the delay is more than five years, the early substantiation will be out-of-date and will not be a basis for an exemption from

substantiation under the review plan rule. See 40 CFR 710.37. If the delay is equal to or less than five years, then TSCA section 8(b)(4)(D)(i) exempts the request to maintain the confidentiality claim for chemical identity from further substantiation requirements.

EPA agrees that substantiation responses provided should be up-to-date and robust as these will be what the Agency will be relying upon in making the required determinations. Similarly, while submitters may choose not to substantiate CBI claims for chemical identity substantiated within the five-year period specified by the Administrator, manufacturers and processors, recognizing that the Agency will be relying on these in making determinations, may find it prudent to substantiate in accordance with the review plan to ensure that the substantiations are up-to-date and comprehensive.

Comment 41: One commenter stated that this rule should require the submission of substantiation for chemical identity CBI claims at the time an NOA Form A is filed, rather than just allowing for such submission.

Response: Such action is beyond the scope of this rule. Under TSCA section 8(b)(4)(C), EPA must establish a plan to review all claims to protect the specific chemical identities of chemical substances on the confidential portion of the Inventory. In the interest of meeting the June 22, 2017 statutory deadline for issuing a rule under TSCA section 8(b)(4)(A), EPA elected not to concurrently promulgate a rule establishing this review plan. EPA intends to compile the initial list of active substances as soon as practicable following the close of the retrospective submission period for processors, and it must finalize the review plan rule within one year of issuing that compilation. See TSCA section 8(b)(4)(C).

Comment 42: One commenter stated that the rule needs to specify the types of chemical identity CBI claims in other submissions for which EPA will consider a prior substantiation sufficient.

Response: Such action is beyond the scope of this rule. This will be considered when promulgating the review plan rule under TSCA section 8(b)(4)(C).

Comment 43: *One commenter stated that EPA needs to make clear that requirements of section 14 apply to CBI claims asserted and reviewed under section 8 and that the public information requirements of section 8(b)(7) apply to chemical identity claims under both sections 8 and 14. The commenter elaborated that EPA should integrate claims reviewed under section 8 into the systems it develops pursuant to section 14 for tracking the results of those reviews and for making public information on the status of claims and information that is not or no longer protected.*

Response: EPA agrees that the requirements of TSCA section 14 generally apply to CBI claims made in this collection. Exceptions to this general application include the claim maintenance, substantiation, and review processes set forth in TSCA section 8(b)(4)(B)-(E) and 8(b)(5)(ii). Pursuant to section 8(b)(4)(C), the Agency will promulgate a separate rule that establishes a plan for reviewing, and requirements for substantiating, requests to maintain existing CBI claims for specific chemical identity.

Comment 44: One commenter stated that substances should not be moved from the confidential Inventory to the public Inventory until the close of the applicable notification periods. Another commenter indicated that in the absence of valid claims to maintain a confidentiality claim for specific chemical identity, EPA should promptly make the information public, and in the case of retrospective reporting, should specify a deadline for doing so. The commenter believes this should be done no later than compiling the version of the Inventory containing active and inactive designations. A few commenters stated that EPA should provide advance notice to the claimant and the public before moving substances from the confidential Inventory to the public

Inventory, e.g., so that potentially affected manufacturers and processors have an opportunity to reassert CBI claims.

Response: TSCA section 8(b)(4)(B)(iv) is clear that, in situations where no one requests to maintain a claim of confidentiality for specific chemical identity, an active chemical substance must be moved from the confidential portion of the Inventory to the public portion of the Inventory. EPA will not move substances that are on the confidential portion of the Inventory to the public portion of the Inventory until after the retrospective submission periods close and EPA has determined that no notices were received seeking to maintain an existing CBI claim for those substances. EPA has developed clear rules, mirroring statutory text, for requesting to maintain a claim of confidentiality for specific chemical identity. EPA is not establishing by this rule an additional process for providing advance notice when it will move substances from the confidential portion to the public portion of the Inventory. However, EPA practice is to notify original claimants and/or the public when it has moved substances from the confidential portion to the public portion of the Inventory, e.g., through direct contact with the original claimant or publication of a **Federal Register** notice.

EPA agrees with the comments on the need to develop procedures for the prompt updating of the public portion of the Inventory when a chemical substance previously listed on the confidential portion of the Inventory no longer qualifies for that status. Because of the volume of NOA Form A's anticipated, the Agency cannot commit in advance to a timeframe for updating the public Inventory. Therefore, EPA is also not establishing by this rule a deadline for moving substances from the confidential portion to the public portion of the Inventory if no one requests to maintain a claim of confidentiality for specific chemical identity during retrospective reporting. EPA will provide information on this activity as soon as is practicable after processing

all notices received and determining which confidential substances can be moved to the public portion of the Inventory.

Comment 45: One commenter stated that substances on the confidential portion of the Inventory but not produced in the 10-year lookback period will automatically lose their confidential status, and indicated that EPA should specify a mechanism to protect the confidentiality of substances not in production during the look-back period.

Response: Substances on the confidential portion of the Inventory but not produced in the 10-year lookback period will not automatically lose their confidential status. TSCA section 8(b)(4)(B)(iv) requires that EPA move "any active chemical substance for which no request was received to maintain an existing claim" to the public portion of the Inventory, but does not require the same action to be taken with respect to inactive substances, and EPA has not proposed taking such action with respect to inactive substances. Rather, TSCA section 8(b)(5)(B)(ii) allows persons reintroducing an inactive substance into U.S. commerce to seek to maintain an existing CBI claim for specific chemical identity at the time of their NOA Form B submission. This statutory provision envisions that inactive substances will typically have retained their confidential status up until their reactivation; otherwise, there would be no existing CBI claim to seek to maintain. Those persons who later report the substances in the forwarding-looking reporting process and who seek to maintain an existing claim of confidentiality for specific chemical identity must comply with the processes set forth in the regulations at 40 CFR 720.37(a)(2). The Agency will then review the claim in accordance with TSCA section 14.

Comment 46: Another commenter stated that EPA's proposed substantiation questions inappropriately suggest that CBI claims in Inventory notifications could lead to permanent protection from disclosure.

Response: As noted in another Response, EPA has amended the substantiation questions. EPA observes though that CBI claims are subject to all the limitations contained in TSCA section 14, including those related to duration of protection from disclosure provided at TSCA section 14(e) and also additional review as provided at TSCA section 14(f).

Comment 47: Two commenters requested that EPA clarify the term "processing" and the definition of "processor." Another commenter stated that EPA should conform proposed definitions to those terms actually used in the statue, citing "[m]anufacture or process for a nonexempt commercial purpose" as the only manufacture or processing term that is necessary to define for this rule. The commenter also states that the new definition for "[I]nventory" could be misinterpreted as a fundamental change in the TSCA Inventory. A third commenter stated that existing definitions should be maintained, citing that the revised definition for "manufacture for commercial purposes" is incorrect and inconsistent.

Response: EPA generally addressed the definitional comments in the proposal published on January 13, 2017 (82 FR 4255) and EPA restates the reasoning: "EPA believes that basing Section 8(b) definitions that are already familiar to the public from CDR and PMN reporting would reduce the potential for confusion and reduce the burden of rule familiarization. EPA is not proposing to modify the 40 CFR part 710 definitions in any manner that either is not conforming to Part 704, 710, or 720, or is a purely technical correction (e.g., eliminating references to the Canal Zone from the definition of ''State''). Any other changes to the definitions in 40 CFR part 710 are beyond the scope of this proposal."

Comment 48: One commenter stated that both this rule and EPA's prioritization rule need to specify how EPA will decide whether or not it is necessary to determine the priority of a newly activated chemical.

Response: The review referenced under TSCA section 8(b)(5)(B)(iii)(IV) is to occur "pursuant to [TSCA section 6(b)]." This comment, therefore, is beyond the scope of this rule. EPA did not seek in the proposed rule to establish prioritization-related procedures under TSCA section 6(b), specifically applicable to chemical substances that have become active following a period of inactivity.

Comment 49: Two commenters suggested that, although processors are not required to participate in retrospective reporting, EPA should encourage processors to do so.

Response: EPA reiterates that processors have the option to simply not report under TSCA section 8(b)(4), and can continue processing until the effective date of EPA's designation of a chemical substance as inactive on the Inventory. At such time, however, any further processing of an inactive substance for a nonexempt commercial purpose will be prohibited by TSCA section 8(b)(5) without prior notification to EPA. 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).