March 14, 2017

Document Control Office (7407M)
Office of Pollution Prevention and Toxics (OPPT)
Environmental Protection Agency
1200 Pennsylvania Ave., N.W.
Washington, DC 20460-0001

Sent electronically to www.regulations.gov

Re: Comments of the American Chemistry Council on TSCA Inventory Notification (Active-Inactive) Requirements – Proposed Rule; EPA-HQ-OPPT-2016-0426; 82 Fed. Reg. 4255 (January 13, 2017)

Dear Sir/Madam:

The American Chemistry Council (ACC)[1] is pleased to comment on the Environmental Protection Agency's (EPA) Proposed "Inventory Reset" or "Reset" Rule, one of three major framework rules required by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA), amending the Toxic Substances Control Act (TSCA). The long-term success of LCSA depends on a systematic, timely process of chemical risk evaluation, and the Inventory Reset is the first step of that process.

As EPA has stated in the preamble to the proposed rule, the Reset has two purposes. The first is to sort the chemicals on the Inventory for their status as either active or inactive in commerce. This sorting is integral to the risk evaluation process, as chemicals that are active in commerce will then be prioritized for risk evaluation. The second is to ensure that confidential business information (CBI) claims for chemicals on the confidential portion of the Inventory are current. The statute uses a notification procedure to achieve the first objective, and a procedure to require that existing CBI claims be maintained for the second.

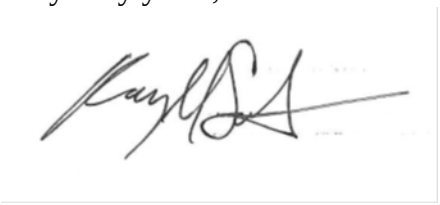
The Reset required by LCSA is not a small undertaking; the Inventory currently contains approximately 85,000 entries. Chemical manufacturers bear the central burden of the Reset, as they have a mandatory statutory duty to participate in the notification process to effect the Reset. Our fundamental interest in this rulemaking is to ensure that the Reset process is as efficient as possible, avoids duplicate notifications and unnecessary burden on industry, and yields an accurate result. This interest is entirely consistent with statutory direction at TSCA § 8(a)(5)(A) and cited in the preamble to the proposed rule,

1 The American Chemistry Council (ACC) represents the leading companies engaged in the business of chemistry. ACC members apply the science of chemistry to make innovative products and services that make people's lives better, healthier and safer. The business of chemistry is a $797 billion enterprise and a key element of the nation's economy. The products and processes employed by chemistry companies are significantly regulated under the Toxic Substances Control Act.

which specifically states that the regulation should avoid requiring notification that is "unnecessary or duplicative."

Thank you for the opportunity to comment. If you have any questions, please contact me at: 202-249-6130 or Karyn_Schmidt@americanchemistry.com.

Very truly yours,



Karyn M. Schmidt
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American Chemistry Council

cc: Jeffrey Morris, Director, Office of Pollution Prevention and Toxics
Myrta R. Christian, Chemistry, Economics, and Sustainable Strategies Division

Comments of the American Chemistry Council on
Proposed Inventory Reset Rule

March 14, 2017

The American Chemistry Council (ACC) appreciates the opportunity to comment on the Environmental Protection Agency's (EPA) proposed Toxic Substances Control Act (TSCA) Inventory Notification Rule (Inventory Reset Rule). EPA has outlined a proposal that delivers a largely simple notification process as envisioned by the Lautenberg Chemical Safety Act. We offer three general comments that support key design features that should remain in the final rule: that EPA should seek additional opportunities to avoid duplicative reporting; should encourage but not mandate processors to participate in the Reset; and should maintain the segregation of the Confidential Business Information (CBI) substantiation process until the Reset is completed. We then outline a number of specific comments and suggestions to achieve greater efficiency and further reduce the burden of the Reset process.

General Comments

EPA Should Apply the TSCA § 8(a)(5)(A) Admonition Not to Require Unnecessary or Duplicative Reporting to Every Element of the Proposed Rule.

EPA identifies two objectives for the Reset: 1) to determine which reportable substances are active in U.S. commerce, and 2) for active chemicals on the confidential Inventory, to require reassertion of existing CBI claims for chemical identity. TSCA § 8(a)(5)(A) also specifies that, to the extent feasible, the regulation should avoid requiring reporting that is "unnecessary or duplicative."

EPA's proposal is generally well-tailored to avoid unnecessary or duplicative notifications. It could be further refined, however, to reduce burdens on both the agency and industry. First, the proposal requires multiple manufacturers to repeatedly notify the agency of the same information – that a chemical on the Public Inventory is active in commerce. EPA can reduce this burden with a simple, single notification made by any manufacturer or processor. Second, EPA should eliminate any requirements to collect and report information beyond what the statute requires; the requirements to report manufacturing dates and type of manufacturing should therefore be removed. Third, a simpler approach to reporting imports of mixtures should be offered.

As EPA considers comments on this proposal, we urge the agency to carefully evaluate each provision of the proposed rule, as well as the operation of the rule in total, to ensure that regulatory requirements and any information sought are necessary to meet the objectives of the Reset. Where EPA already has knowledge that a chemical is active in commerce from an EPA-managed program or reporting requirement, EPA should acknowledge this fact and not require duplicative reporting of the same information.

EPA Should Retain the Proposal to Allow Processors to Report After Manufacturers.

EPA's proposal to allow manufacturers to report first, followed by a voluntary period for processors to report, is efficient and should reduce the reporting burden on processors. We believe it does succeed in

minimizing the potential for processors to file duplicative reports for active substances already identified by manufacturers. We suggest that EPA make two additional clarifications. First, EPA should clarify that processors may also voluntarily report in the 180-day manufacturer period. This may not be readily apparent from the rule itself, particularly for processors who are unaccustomed to and unfamiliar with Chemical Data Rule (CDR) reporting. Second, while it is clear that processors are not required to make notifications, it would be helpful if EPA strongly encourages them to do so, and explains the benefits of participating in the Reset. These additional clarifications could be offered in instructions, fact sheets, and Questions and Answers that accompany the rule.

Substantiation of CBI Claims Should Remain in a Separate Process, as EPA Proposes.

EPA has proposed to separate the reassertion of confidentiality of specific chemical identities from the substantiation of these CBI claims. This approach is appropriate and prudent, given the significant resource commitment that will be necessary to identify active substances within a short time frame. Likewise, EPA's recognition of the need to allow CBI claims to be reasserted by someone other than the initial claimant is appropriate. EPA of course should not move any chemicals from the confidential Inventory to the public Inventory until the close of the applicable notification periods – and after appropriate advance notice to the claimant -- to ensure that all potentially affected manufacturers and processors have had a full opportunity to reassert CBI claims. EPA must ensure that if an "early" notifier decides to waive an existing CBI claim, that action cannot itself prejudice subsequent notifiers or deprive them of an opportunity to reassert a claim.[2]

Specific Comments

1. **EPA Should Acknowledge Active Chemicals in Commerce of Which It Has Knowledge without the Need for Redundant Notifications.**

The statute requires that before EPA publishes the Inventory Reset rule, it must designate an interim list of active substances for purposes of prioritization under TSCA § 6(b). This interim list is necessary for prioritization purposes because the prioritization rule will be finalized in June, 2017 well before the Inventory Reset has been completed. The interim list acknowledges that chemicals from the most recent CDR submission period constitute active chemicals in commerce. EPA proposes to include chemicals from both the 2012 and 2016 CDR submission periods to constitute the interim list; we support this proposal. In particular, we encourage EPA to release the 2016 data as soon as possible, and before the date of promulgation of the rule, to assist manufacturers, importers and processors as they prepare for the notification period(s).

EPA proposes to use this interim list for another purpose: because the interim list is a statutory acknowledgement that CDR-reported chemicals from the most recent cycles are, in fact, active chemicals in commerce, EPA can take note of this fact and need not require additional, manufacturer-specific notifications to be filed. Manufacturer notifications would be redundant of information EPA already has as a consequence of recent reporting completed with the agency. ACC strongly supports this proposal.

[2] This principle also applies to any interim list of active substances. Additional clarification from EPA that any early waivers of CBI claims will not affect the CBI status of the chemical unless and until the process is complete would be helpful.

We encourage EPA to expand on this sensible, practical, and efficient principle – one that we believe is well-grounded in the Section 8(a)(5)(A) charge to avoid unnecessary and duplicative reporting. In short, EPA should not require duplicate reporting of any non-confidential substance for which the agency already has reliable and readily available information to confirm manufacture during the lookback period. For example, any substance for which EPA has received a Notice of Commencement (NOC) reporting manufacture or import during the lookback period clearly meets the definition of an active substance.[3] Duplicate reporting of substances for which EPA already has data to establish that the chemical substance was in active commerce during the lookback period is unnecessary.

The "interim list" is defined by statute, but EPA is in no way limited to the use of this list as its only mechanism to acknowledge active[4] chemicals in commerce. If EPA believes another descriptive term or list is needed, it could introduce a new term for substances for which notification need not be made, such as the "preliminary list of active substances." The "preliminary list" could then encompass all non-confidential substances for which the agency already has the requisite information (e.g., CDR, NOC, Low Volume Exemption (LVE), other) to confirm active status within or after the lookback period, and for which additional notification is unnecessary.

2. The Proposed Requirements to Report a Date Range and to Differentiate Domestic Manufacture from Importation are Unnecessary and Should be Removed.

By statute, a substance qualifies as active if it was domestically manufactured or imported at any time during the lookback period. The statute does not require reporting of date ranges nor particular documentation of the date (or date range) a chemical was manufactured or imported. Since a single occurrence of manufacturing (including importation) during the lookback necessitates classification of the chemical as active in commerce, reporting of the dates of first and last manufacture is meaningless for purposes of the Reset.[5] Locating records to establish conclusively first and last dates of manufacture would be significantly more burdensome than the effort to simply verify that a substance had been manufactured during the relevant period. This is particularly the case when companies or business units have been sold, shut down, or merged.

We do note EPA's explanation that it seeks date range information to reduce the likelihood of receiving erroneous information, e.g., notices regarding commercial activity outside the lookback period. To verify that commercial activity occurred during the lookback period, requiring the identification of a date range seems to have little additional value for validation purposes compared to simply confirming that a reported single date falls within the lookback period. The statute does not require the identification, collection, and reporting of this additional information, and it adds substantial burden to the notification effort. It remains our view that a certification should be sufficient to demonstrate active

[3] See attached spreadsheet, Attachment A, which is a rough approximation of the NOCs received by EPA for the lookback period. This helps illustrate the general volume involved. EPA can substantially reduce reporting burden further by simply taking notice of these NOCs and not requiring duplicative reporting. Since EPA manages this information already, it should be simple for EPA to take note of this information.

[4] We appreciate that "active" status acts as a separate statutory trigger to qualify a chemical for prioritization, so it is important that until the Reset has been completed, EPA use manufacturer reporting and notifications made under TSCA as the basis for agency acknowledgement of active status.

[5] The statutory scheme sets out a clearly defined lookback period for purposes of determining whether a chemical is active in commerce. Due to this feature, there may be cases where a chemical is no longer active in commerce as a matter of fact as of the time of the Reset, but because it was manufactured or imported during the lookback period, it is nonetheless deemed active as a matter of law solely for Reset purposes. The result could be "currently inactive" chemicals being ascribed an "active" designation at the end of the Reset period. While this information could be relevant in the prioritization process on a case-by-case basis, we do not believe the burden of requesting date range information for all chemicals subject to notification in the Reset justifies the request and that it is not necessary for achieving the Agency's stated purpose for the Reset rule.

status in commerce.[6] We also note that EPA did not require documentation of the date of commercial activity when the initial Inventory was established, and do not believe there is a basis to do so now.

Differentiation between domestic manufacture and importation has no bearing on qualification as an active substance. While we appreciate that this information may be of interest to EPA during risk evaluation, the Agency should obtain the specific, current information it needs during the scoping period for risk evaluation. The added burden to industry does not justify including this question as part of the Reset.

3. EPA Should Regularly Post an Updated, Current List of Substances Identified as Active During the Reset – "One and Done."

EPA proposes that each manufacturer must report every non-exempt chemical manufactured during the last 10 years. Because many chemicals are manufactured by more than one company, the agency will receive multiple reports of manufacturing for a given chemical. Only one notification is needed to identify an active chemical. All subsequent reports are duplicative and unnecessary, and impose an unnecessary burden on industry as well as EPA.

A more efficient alternative would be for EPA to post on its website a current list of all chemicals identified as active to date, which would allow manufacturers to avoid duplicative reporting of chemicals already identified as active. EPA should post a first list of active substances as soon as possible and then frequently update the list as additional substances are identified as active throughout the entire reporting period.

This approach would minimize the cost of compliance to small manufacturers and processors by eliminating the need for reporting of substances already identified as active by another regulated entity. It would potentially reduce the need for joint submissions by importers and their foreign suppliers of proprietary mixtures. If a foreign supplier can certify to its importer customer that all components of the proprietary mixture are listed on EPA's posted list of active substances, there would be no need for joint submission or disclosure of the composition of the proprietary mixture. This would also allow foreign suppliers more time to determine whether substances in their mixtures are listed as active substances. We strongly urge EPA to offer a protocol that avoids the need for joint submissions and more flexibly allows either party to make the active notification.

Although TSCA § 8(b)(9) requires each manufacturer to provide a certification, this could be accomplished without the need for redundant reporting of substances already identified as active. Manufacturers could be required to certify (once) that all the non-exempt substances they have manufactured within the applicable time period appear on EPA's most current list of active substances, or if not, that the manufacturer is reporting all additional active substances concurrently with the certification statement.

4. EPA Should Provide Additional Time for Joint Reporting.

Joint reporting with foreign suppliers of proprietary mixtures presents significant challenges. Foreign entities that do not directly import chemical substances into the U.S. are unlikely to be familiar with the requirements of the Reset rule, nor are they likely to be familiar with use of EPA's CDX. While some

[6] If date verification is required, no more than one single date for which manufacture (including import) has been verified during the lookback period should be required.

foreign companies may have experience reporting for the CDR, they will represent a small fraction of those potentially subject to joint reporting for the Reset. For example, some foreign suppliers of polymers may be unfamiliar with CDX, since most polymers are exempt from the CDR. More important, the volume thresholds for CDR reporting exempt many minor components of complex imported mixtures.

Under CDR reporting requirements, when it can be conclusively determined that a component in an imported mixture from a foreign supplier cannot exceed a CDR reporting threshold, there is no need for the supplier to disclose the component's chemical identity, or to engage in joint reporting for the CDR. Certification from the supplier that the component is on the TSCA Inventory is sufficient in those cases. Conversely, for purposes of the Reset, all these transactions would require complete disclosure of mixture constituents, or alternatively, joint submission by the foreign supplier, because there is no volume threshold for Reset notifications. This will pose novel reporting complications for importers of substances into the U.S. in mixtures.

Because U.S. importers may have many foreign suppliers of imported mixtures, significant time and effort may be required to identify the responsible parties, communicate these new requirements, and educate foreign suppliers. The supply chain for many critical products used by industrial, military and other consumers can be highly complex, with importers of formulated products themselves purchasing mixtures from foreign suppliers. These same foreign suppliers may themselves buy ingredients from other upstream manufacturers. Where disclosure agreements are not currently in place for proprietary mixtures from foreign suppliers, lengthy negotiations to permit disclosure that would allow direct reporting by the U.S. importer may be required. Alternatively, if joint submission is the chosen path, explanation and guidance on Chemical Data Exchange (CDX) procedures for the foreign suppliers may be necessary. For imports that occurred several years ago, supply chains may have changed, business relationships with a past supplier may no longer be in place, suppliers may have divested products, and other circumstances may exist that will require significant time and attention. EPA should allow the U.S. importer to report within the 180-day period required by the statute, but allow additional time for submission of information by the foreign joint submitter. We suggest this additional time period could be concurrent with the additional 180 days allowed for processor reporting.

As noted above, if EPA adopts the recommendation for publishing a regularly updated list of substances already reported as active, including the expanded "preliminary list" recommended above, these actions should facilitate communication with foreign suppliers. If a supplier can determine that some or all of its mixture components have already been listed as active, certification of this fact to the U.S. importer would obviate the need for the supplier and importer to discuss those components any further. We would suggest that a list of chemicals reported as "active" could be posted to a public website daily, as well as on CDX, in an exportable format so manufacturers and importers can compare EPA's posted list with their internal company lists.

EPA should also recognize that some of this chemical identity information from past imports may no longer be reasonably ascertainable, for the reasons noted above. The consequence of such a situation would be that a substance that had been imported at low volume within the past 10 years would be incorrectly designated as inactive, since no party will have reported it. However, any future importer would be responsible for obtaining the necessary chemical identity information for the "inactive" substance prior to actual importation to support a forward-looking notification under TSCA section 8(b)(5)(B).

5. **EPA Should Establish a Formal Mechanism and Time Period for Corrections to the Active List.**

EPA established a mechanism for corrections to listing on the original TSCA Inventory. The agency should anticipate that some errors will occur in the significant undertaking that is the Inventory Reset and offer a discrete process to ensure that corrections can be made on a timely basis. We also suggest that EPA communicate a process to facilitate these corrections and establish a reasonable time period during which corrections can easily be made.

6. **EPA Should Allow Nomenclature "Alerts" and Other Organizational Information to be Voluntarily Offered During the Notification Process and Should Commit Dedicated Resources to Resolving Nomenclature Issues.**

Certain nomenclature standards have evolved over the nearly 40 years the TSCA Inventory has been in existence. The Reset will inevitably trigger a significant number of questions concerning interpretation of nomenclature used for specific Inventory listings. Given that the Reset is critical to prioritization and risk evaluation under the LCSA, it is essential that identical chemical substances not simultaneously bear both "active" and "inactive" classifications after the Reset is completed, and it is also important that linkages between chemically equivalent substances not be lost in the Reset process.

EPA may make nomenclature equivalency determinations under the LCSA. To facilitate the agency's ability to reach these determinations, we recommend that EPA include, on Form A, an opportunity for notifiers to voluntarily "alert" EPA to equivalent substances that may warrant an equivalency determination at a later date. Text could be added to Form A (and Form B) as follows, allowing notifiers to "check a box" to alert EPA to a follow up Inventory management action:

> *Optional: Based on knowledge of chemical identity, the chemical substance [CASRN/other] may be chemically equivalent to [CASRNs/others] and eligible for a nomenclature equivalency determination pursuant to TSCA Section 8(b)(3)(B).*

In the alternative, CDX could support the separate submission of nomenclature "alerts" to EPA. Regardless of the approach taken, given the compressed time frames set out by statute for the Reset, EPA should identify, in advance, its technical experts in the agency who will be equipped to answer questions concerning existing Inventory nomenclature and resolve problems.

With respect to classification and equivalency, it has been noted that some chemicals on the Public Inventory have not been assigned CAS registry numbers. This may create complications in the notification process. EPA may wish to refer chemicals to CAS-IES for CAS registration numbers as part of the Reset, or publish a process by which manufacturers may contact EPA for CAS numbers or other equivalent information. Nomenclature equivalency considerations should also be addressed as part of this referral.

Other circumstances may warrant allowing notifiers an opportunity to "flag" specific nomenclature or nomenclature-related circumstances for EPA that may require correction, reconciliation, or notation either of or on the Inventory or otherwise. These additional options to "flag" information could include an opportunity to voluntarily designate chemicals on the public Inventory with no CAS number assigned (chemicals on the confidential Inventory should be identifiable by accession number), to designate chemicals with duplicate entries (not otherwise flagged for possible nomenclature equivalency, as

discussed above), to designate chemicals with different nomenclature internationally, or to identify chemicals that implicate the statutory mixtures provision at Section 8(3)(A)(iii).

In addition, we note that Section 26(l) of TSCA requires EPA to develop any policies, procedures, and guidance needed to carry out the LSCA amendment within two years of the date of enactment, or by June, 2018. This statutory mandate aligns well with the Inventory Reset itself, which is scheduled to begin in June, 2017 with the promulgation of the final rule initiating the manufacturer notification period. Guidance could be developed that describes how EPA will address inconsistent nomenclature conventions, and how it will facilitate assignment of CAS registry numbers to chemicals on the Public Inventory lacking them (or what the alternative identifier will be). Guidance could also describe and administer a "reconciliation" period following the manufacturer and processor notification periods to allow EPA to act fully on information reviewed or collected as part of the Reset process, and to ensure time to address corrections and errors in notification and other quality assurance measures.

We also encourage EPA to consider issuing an interim enforcement policy, contemporaneously with the Inventory Reset rule, to clarify that the agency will not pursue enforcement of good faith notification errors. An added benefit of this policy is that it could increase processor participation. The Reset will be a big undertaking, and with statutorily mandated, compressed deadlines, enforcement relief will help facilitate early participation in the reset. This approach is also justified due to the purposes of the Reset – a one-time, ministerial notification of "active" status that helps operationalize the prioritization and risk evaluation functions of a revised TSCA, rather than more detailed and ongoing reporting regulation.

7. EPA Should Provide Additional Clarification of Application of the Rule to Polymers.

We understand EPA's proposal to require polymers that are listed on the Inventory, but do not otherwise appear on the interim list of active substances, to be subject to the notification requirement as part of the Reset. It would be helpful if the preamble offered this additional clarification.

We suggest EPA clarify that it intends to continue the availability (and applicability) of the Free Radical Initiator Rule (FRIR)[7] during and after the Inventory Reset has been completed. Including a specified grandfather period would be particularly helpful. EPA should consider republishing an update of the FRIR as part of its 2-year obligation to update policies, procedures and guidance under Section 26 of the amended statute.

8. EPA Should Clarify that Information is Not "Reasonably Available" if It Is Not in the Possession, Custody or Control of the Manufacturer or Importer.

The 10-year lookback period may significantly exceed some companies' record retention policies, and it exceeds TSCA five-year record retention requirements. Companies may also no longer have manufacturing or import records available following a merger, sale, or other corporate transaction. While in some cases, a company may have actual knowledge that it manufactured or imported a chemical within the lookback period without the support of documentation; in other cases, a company might not have such knowledge, and may lack any documentation due to company sale, divestment or other circumstance. EPA should clarify that if a company no longer has a TSCA-based legal obligation

[7] 54 Fed. Reg. 27174 (Jun. 28, 1989).

to maintain particular records of manufacture or import, or another company has legal possession, custody and control of the records, notification by that company is not required.[8]

An important related question requiring clarification, particularly in the case of sales, mergers, and divestments, is which company has the obligation of making the "active" notification as part of the Reset? The proposed rule is not clear which corporate entity has the obligation, or option, to notify. We recognize that current CDR guidance is that the company at the time of the submission period is responsible for reporting the active manufactured and imported chemicals.[9] We also recognize, however, that the Inventory Reset has a much lengthier look back period than a typical CDR submission cycle, which spans more business activity and more changes to corporate entities and production, and will thus likely add significant complexities and complications to the notification process. We also note that many corporate divestment cases, entities may have decided between themselves which would bear responsibility for prospective reporting obligations, even for events occurring before the divestment. It will be essential to offer clarification on these points before the notification period begins. EPA can alleviate some of this complexity by further reducing the overall notification burden as addressed in our other recommendations in these comments, such as acknowledging the active status of NOCs and LVEs from the start of the lookback period to the present, implementing the "one and done" approach to notification, and by relieving companies of the burden of seeking records not in their possession.

9. EPA Should Offer More Information About Use of the CDX for the Reset.

ACC appreciates that EPA is working on a statutory mandate to complete this rulemaking, and it may not be practicable to launch a help desk, training, and support materials on use of the CDX for the Reset before the promulgation of the final rule. Nevertheless, we urge EPA to release these materials as soon as possible after the rule's publication. We encourage EPA to offer XML functionality for multiple/batch loading into the CDX, as offered by the CDR program in CDX for the 2016 submission period. We also encourage EPA to carefully consider whether CDX will be able to support the size and scale of this notification activity, given the difficulty CDX had in the 2016 submission cycle handling the volume of submissions. This activity may be significantly more complicated by the removal of a volume threshold for Reset notification, the participation of foreign entities (who may need supplemental help desk support and tailored instructions), the reporting of polymers, and the influx of joint submissions.

EPA may wish to consider connectivity and data import/export features between the CDR platform on CDX and the platform to be used for the Inventory Reset notifications. Registrations and name changes should also be considered. During the 2016 CDR submission period, issues often arose from company name changes, corporate changes, and divestures.

ACC suggests that EPA consider CDX "beta testing" in advance of the launch of the manufacturer notification period, or at least as early in the process as possible. The burden of making Form A submissions on some companies will be substantial, and any system incompatibilities, software issues,

[8] An example of this might be a sale or other divesture, as with a company that did manufacture a chemical during the lookback period but no longer does or has divested the unit that did.

[9] "Company X and Company Y should determine, based on the circumstances of their reorganization, whether Company Y was created as the continuation of the part of Company X that previously conducted the manufacture of the pertinent substance(s). If Company Y is the continuation of the part of Company X that manufactured the pertinent substance(s), then Company Y reports based on all the manufacturing that Company X did in [submission period], including the manufacturing that it did while it was a unit of Company X." EPA, Fact Sheet: Reporting After Changes to Company Ownership or Legal Identity, January 2016, available at https://www.epa.gov/chemical-data-reporting/fact-sheet-reporting-after-changes-company-ownership-or-legal-identity

and so forth will need to be identified and resolved expeditiously. While we have noted the issue of certain chemicals on the Inventory lacking CAS numbers as one deserving further guidance, if CDX is to be used as the notification platform beginning in June, 2017, immediate modifications will be needed for the system to recognize and accept submissions for chemicals lacking CAS numbers. If EPA wishes to instruct manufacturers and processors to obtain CAS numbers before making notifications, that guidance should be issued promptly to the regulated community, and EPA may wish to request that CAS prioritize such requests.

10. Form A and Form B Should Bear More Descriptive Titles and Be Otherwise Modified to Conform with Recommendations.

As currently drafted, the intended uses for Forms A and B are not obvious from their titles. Potential confusion could be prevented by using unique titles, such as Notice of Past Activity of Manufacture, Import, or Processing – Form A; and Notice of Anticipated Activity of Manufacture, Import, or Processing – Form B. Consistent with the recommendations made above:

- Form A should be modified to delete the requirement to specify a date range and to eliminate the distinction between domestically manufactured and imported substances.
- On Form B, the instructions should make clear that only one activity (domestic manufacture, import, or processing), with relevant start date for manufacture, needs to be reported.
    - If domestic manufacture or import is anticipated to occur, it should not be necessary to provide a date anticipated for subsequent processing, since it is only the first activity that will change the substance's status from inactive to active.
    - Similarly, if a processor is submitting Form B for anticipated processing of an inactive substance, the form should not create the erroneous impression that the processor must try to somehow determine a date in the past when the substance had been manufactured or imported by another party.
    - The term "and/or" in the instructions in Part II should be replaced by "or," so that the sentence reads, "Date is the actual date when the inactive chemical substance is to be domestically manufactured, imported, or processed commercially for non-exempt purpose."

11. The Rule Should Offer a Reasonable Opportunity to Rescind or Update Form B as Circumstances Warrant.

The statute requires advance notice to EPA before manufacturing or processing of an inactive substance. As proposed by the rule, a Form B may be submitted any time before commencing manufacture, but not more than 30 days before. This is a reasonable proposal, and helpful in that it allows manufacturers and processors time to plan and submit the notification well before manufacturing actually starts. There may, however, be circumstances when a manufacturer submits its Form B and then manufacturing is delayed past the 30-day period or does not occur at all. In such cases, the rule should allow submitters a reasonable opportunity to update or rescind the Form B notification, as appropriate, to reflect whether and when manufacturing or processing actually began.[10] CDX could support the "correction" and "rescind" actions for Form B on this platform.

[10] Reactivating an inactive-status chemical on the Inventory is a simple process that is a ministerial function of the notification. For that reason, any "errors" in the actual notification, such as an unsigned certification, should likewise be correctable within 30 days of submission without penalty. This is also important to accommodate system outages or other problems with the CDX platform.

12. EPA Should Clarify the Status of Chemicals Manufactured or Processed In the "Gap" Between the Date of Enactment and Date of Finalization of the Active/Inactive Lists.

Under the proposed rule, there may be chemicals that were manufactured before June 22, 2006, but not manufactured or processed in the statutory lookback period, and were again manufactured or processed on or after June 22, 2016. Thus these chemicals may be currently in "active commerce" but "skip" the operation of the lookback period, so notice is submitted. EPA could address this scenario in the Reset by allowing optional active notification of chemicals outside the lookback period where manufacturing or processing occurred on or after June 22, 2016; in the alternative, EPA should clarify that Form B may be used to make these notifications during the Reset.[11]

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Corrections:

- Proposed 710.29(b)(2) addresses manufacturing, importing, or both. This section should be amended to include processors (processing added to the list of specified commercial activities) or a separate section added to address processor reporting.

Miscellaneous:

- It would be helpful if EPA could clarify that it intends to continue the availability (and applicability) of the Free Radical Initiator Rule (FFIR) during and after the Inventory Reset has been completed.

[11] Due in part to the lengthy lookback period, strict application of the proposed process could also result in a company being required to "notify" EPA of the active status of a chemical it no longer manufactures (or processes) and never plans to manufacture (or process) again. The Reset thus may result in "active" chemical in commerce notifications occurring where, in fact, manufacture/import and processing of a chemical has completely ceased. While the Reset is a simple notification process and we do not support additional mandates for collection of information, EPA should allow companies voluntarily to provide or "flag" this additional information in such cases.

Appendix – Burden Estimate

EPA appears to have significantly underestimated the regulatory burden of compliance with the Inventory Reset. EPA's analysis suggests two major flaws. First, EPA makes inappropriate assumptions estimating the number of chemicals to be notified for the Reset, as well as the number of firms needing to report, which is a factor used in the overall cost calculation. Second, EPA significantly underestimates the amount of time needed for data gathering, and some of the major activities needed for determining active status are simply not accounted for in the time estimates.

A. Estimates of number of chemicals and number of firms

The number of chemicals (7,690) and firms (1,626) reporting in the 2012 CDR is used as the starting point for estimates. The assessment recognizes that certain classes of chemicals were outside the scope of CDR reporting, but are not exempt from the Reset, i.e., those below the 25,000 lb. CDR threshold and polymers (unless CDR-reportable because of special regulatory status).[12] These classes are referred to in the assessment as "non-CDR non-exempt chemicals." The assessment improperly minimizes the number of non-CDR non-exempt chemicals that need to be added to the CDR universe to estimate the scope of Reset-reportable chemicals. This underestimate apparently is the result of a misinterpretation of the impact of the Low Volume Exemption (LVE) and the Polymer Exemption. The assessment seems to make the assumption that most low volume chemicals and polymers would not be listed on the Inventory, and therefore not subject to the Reset. The assessment fails to acknowledge that many manufacturers have voluntarily elected to add low volume chemicals or polymers to the Inventory by filing a PMN, rather than applying for an LVE or executing a polymer exemption. Furthermore, only a subset of all polymers meet the specific criteria to qualify for a polymer exemption and many polymers have been added to the Inventory via PMNs, even after the polymer exemption rule revision in 1995.

- LVE chemicals: EPA states that the additional chemicals to be included in the Reset would be those with volumes less than 25,000 pounds, but not likely to be greater than 4,545 pounds.[13] The latter number being derived by a miscalculation in the assessment by incorrectly converting the 10,000 kg LVE limit to pounds by dividing by 2.2, rather than multiplying by 2.2. Irrespective of the miscalculation, the assessment simply estimates the number of additional chemicals and firms in this category by assuming a 10% increase over the number of chemicals and firms reported in the CDR, and offers only "Best Professional Judgment" as justification for the use of the 10% factor.[14]

- Polymers: The assessment apparently does not attempt to include any additional polymer chemical or firms in the estimate, unless polymers were intended to be incorporated into the 10% adjustment noted above.

The number of non-CDR non-exempt low volume chemicals and polymers is almost certainly much greater than the estimate of 769 (10% of 7,690) used in the assessment – an underestimate of perhaps an

[12] The numbers are substantial. A cursory review of the TSCA Public Inventory yields 19,043 records flagged as N, XU, Y1, or Y2 (or a combination thereof), none of which are subject to CDR reporting. An additional 1367 records in the Confidential PMN table are flagged as XU. See Attachment A, a compilation of NOCs received by EPA from June 21, 2006 to November 22, 2016 published in the Federal Register. The inclusion of confidential PMNs in the document shows that many records identified only by accession numbers have had NOCs filed during the lookback period (i.e., these accession numbers should be added to EPA's Active List as part of the Reset). For records marked in yellow, we were not able to determine during this comment period whether the record has an accession number.

[13] See page 12.

[14] See page 13.

order of magnitude or more. Surrogate data for making a more accurate estimate of low volume chemicals may be difficult to obtain, but EPA does have information that could be useful to make a more reasonable estimate of CDR-exempt polymers that will be subject to the Reset. By evaluating NOCs the Agency has received over several years, it would be possible to estimate the relative ratio of new polymers to new non-polymers added to the Inventory. That ratio could then be used as the basis for estimating the universe of polymers based on the number of non-polymers reported for the CDR. The actual number of active polymers would likely be even higher than this estimate, since many polymers grandfathered onto the original Inventory are still active in commerce.
EPA also states in the assessment that, "…on average, a given chemical is manufactured (including imported) or processes [sic] by 4.7 firms."[15] This factor may also be useful in providing an updated assessment of the number of firms expected to report for the Reset.

B. Time estimate per response per manufacturer and processor

On page 18, the effort required for "compliance determination," which is stated to include, "...reviewing files to determine whether reporting is required for chemical substance(s) manufactured (including imported) and/or processed by a particular company," is estimated at 0.5 hours per company, regardless of the number of chemicals involved. "Best Professional Judgment" is cited as the basis for this estimate. An additional per chemical burden of 0.083 hours (i.e., 5 minutes) is estimated for reviewing the list of active chemicals, but this is associated only with searching EPA sources, such as the TSCA Inventory or the Substance Registry Service (SRS), for the appropriate chemical ID.

As part of the activities associated with "Form Completion/Submission," the effort required for reporting of "Date Range" is estimated at 0.944 hours per chemical.[16] The assessment states that this activity would require submitters to refer to company records to identify the necessary and relevant information. The estimate is based on what the assessment describes as a similar activity required in Toxics Release Inventory (TRI) reporting for identifying the maximum amount of the toxic chemical on site at any time during the calendar year.

These assumptions seem likely to greatly underestimate the effort needed for Reset reporting. While the TRI analogy may be appropriate for aspects of the Reset reporting, there are significant differences that increase the effort required for reporting of a single chemical under the Reset requirements. First, the 10-year lookback will require a greater effort for location and compilation of records than for a single calendar year record for an established TRI reporting program. The level of effort required will likely increase with the age of the records that must be evaluated. Second, many records, especially for imports, are likely to be based on product identity, rather than chemical identity. Many products are comprised of multiple chemical components. These compositions would need to be broken down into their individual constituents in order to identify the chemical substances to be reported for the Reset. In cases where the imported mixture was obtained from a foreign supplier, additional effort would be required to obtain the complete mixture composition from the supplier. If the supplier considered the composition details to be proprietary information, a confidentiality agreement would need to be negotiated and executed. Alternatively, the foreign supplier would be required to provide the confidential information directly to EPA through a joint submission. This would require the foreign supplier to register and become educated in the use of CDX, all of which would substantially increase the reporting burden.

[15] See footnote 15 on page 13.
[16] See p. 19.

Once the mixture had been broken down into individual components, each component would need to be evaluated to determine whether the component had not been previously identified as reportable, or if this instance was only a duplicate occurrence of an already identified substance. If the requirement to report date range remains unchanged, the occurrence would also need to be evaluated as to whether its date was either the earliest or latest occurrence, or simply fell within an already established range. In fact, reporting the date range is the single activity with the highest estimated burden in all of the steps identified by EPA. Changing the requirement from date range to reporting of any single activity within the lookback period would significantly decrease the burden associated with assessment of the records and the overall effort required for Reset reporting.

For processors, EPA estimates that 161,550 firms will expend 4 hours of effort per firm for familiarizing themselves with the reporting requirements, but that only 100 firms will actually report. Therefore, EPA assumes that the burden for the 161,450 non-reporting firms will be limited to 4 hours each. This assessment ignores the effort these non-reporting firms would need to invest to confirm that all the substances that they process are listed as active and may legally be used, even if they ultimately determine that they have no need for them to submit a Reset notification. The effort involved would require an assessment of each chemical being processed to ensure that it is listed as active or, alternatively, obtaining assurances from each of their suppliers that all chemicals they use are listed as active. Either approach would require a significant expenditure of effort, which is not reflected in the current assessment.

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See Attachment A (Separate Document; Incorporated by Reference)
Compilation of NOCs From June 21, 2006 – November 22, 2016

Attachment A, ACC Inventory Reset Comments PDF of NOCs 062106-112216.zip