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Submitted via REGULATIONS.GOV to Docket: EPA-HQ-OPPT-2016-0426

Dr. Jeff Morris, Acting Director
Office of Pollution Prevention and Toxics
Environmental Protection Agency
1200 Pennsylvania Avenue, N.W.
Washington, DC 20460

Re: TSCA Inventory Notification (Active-Inactive) Requirements;
Docket ID: EPA-HQ-OPPT-2016-0426

Dr. Morris:

The American Cleaning Institute (ACI)[1] is pleased to provide comments in response to the U.S. Environmental Protection Agency's (EPA's) proposed rule implementing requirements to designate substances on the Inventory as active or inactive.[2] These requirements arise from recent amendments to Section 8 of the Toxic Substances Control Act made by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA).[3]

ACI supports U.S. EPA's efforts to achieve the two key objectives identified in the proposed rule, namely:

1) "…to determine which reportable chemical substances are active in U.S. Commerce…", and;
2) "…with respect to chemical substances identified as being active in commerce that are listed on the confidential portion of the TSCA Inventory, to require that persons manufacturing or processing such chemical substances request that existing claims for protection against disclosure for the specific chemical identity be maintained."

General Comment

The proposed rule is well written and is narrowly tailored to meet the two key objectives. ACI agrees with the approach taken by U.S. EPA in the proposal which involves processors participation early in the reset exercise; this ensures processors can promptly inform the Agency of active substance designations for the Inventory that may have been overlooked by manufacturers and importers during the first 180-day reporting period.

To minimize the reporting and processing burden on EPA and on the regulated community, and to minimize the opportunity for omissions, ACI recommends that EPA establish a reporting system

[1]ACI is a trade association for the $30 billion U.S. cleaning products industry. ACI members include the formulators of soaps, detergents, and general cleaning products used in household, commercial, industrial and institutional settings; companies that supply ingredients and finished packaging for these products; and oleochemical producers.
[2]82 Fed. Reg. 4255 (Jan. 13, 2016).
[3]Public Law 114-182 (June 22, 2016).

in which the interim non-confidential active substances list is publicly updated on an on-going real-time basis throughout the reporting periods. This would reduce the number of duplicative reports, thus reducing unnecessary costs and effort. If real-time updates are not feasible, EPA should consider specifying periodic, either weekly or biweekly, updates to reduce burdens on both manufacturers and the Agency.

Specific Comments

Estimated incremental impact of this action

EPA's estimate of the incremental impacts of the reporting burdens is unrealistic. U.S. EPA should take into consideration the considerable number of substances that are not reported for purposes of the Chemical Data Reporting (CDR) that will require reporting for the lookback period. For example, the Agency should consider in its cost estimate the large number of inorganics that would be subject to the retrospective reporting period, which were partially exempt for the years prior to 2012. Likewise, U.S. EPA must consider the significant number of substances which are listed on the confidential and non-confidential portions of the Inventory, but are manufactured or imported in quantities below the 25,000 pound CDR threshold. U.S. EPA also must take into account those substances designated as XU (exempt from reporting under CDR rule, i.e., partial updating of the TSCA Inventory Data Base Production and Site Reports (40 CFR 711)) on the Inventory. One chemical manufacturer estimated that their company maintains over 250 separate substances designated as XU on the current Inventory. One would expect there may be a significant difference in the number of reportable substances that appear on the current Inventory but for which CDR reports were not received in 2012 and 2016; this would also mean there could be a significant difference in cost impact estimates.

In order to lessen the reporting burden, ACI recommends that EPA create a spreadsheet template containing all of the required information fields in the *Notice of Activity of Manufacture, Import, or Processing (NOA) Form A* that can be submitted to the Central Data Exchange (CDX) via xml. The ability to enter and submit data in a spreadsheet format that can be uploaded in one step would significantly reduce the efforts of and burdens on companies that must make multiple submissions.

§ 710.25 Persons subject to the notification requirement (a) and § 710.27 Activities for which notification is not required

While we recognize that there are substances exempted from listing on the TSCA Inventory, such as polymers, low volume substances, and other substances not subject to or exempted from pre-manufacture notification, that are also not subject to this proposed rule, those exemptions are ambiguously stated in these sections. ACI recommends that, for clarity and completeness, a more definitive listing of exempted substances be included. This may partially alleviate the issues noted in the estimated incremental impacts section.

Further to this, other issues can occur. For example, Company A manufactures an exempt polymer and, therefore, does not report it for the TSCA Inventory (but did submit the proper documentation pursuant to the Part 723 regulations). Company B manufactures the same polymer and submits a PMN to list the polymer on the confidential portion of the Inventory, but then abandons the polymer, causing it to be "inactive". It could be interpreted that Company A would inadvertently be in violation of the regulations without knowing that the polymer has become "inactive" on the confidential Inventory. The same scenario applies if a substance is not placed on the Inventory by

one company because of other exemptions (low volume exemption (LVE) or test market exemption (TME)), but may appear "inactive" on the confidential Inventory due to another company's actions. For these reasons, ACI recommends that U.S. EPA exempt all categories of substances for which no reporting is required pursuant to the CDR rules.

ACI recommends that all substances with identities claimed as confidential on the 2016 CDR report be included on the interim active confidential inventory. Substantiation for chemical identity is required at the time of the CDR submittal and, therefore, has been provided within the last 12 months. Furthermore, their import or manufacture during the 10-year reporting period has also been confirmed via the 2016 CDR report. Requiring industry to report these substances for purposes of resetting the TSCA Inventory is unnecessary and redundant.

§ 710.25 Persons subject to the notification requirement (c)
ACI recommends that, consistent with the Notice of Commencement process in 40 CFR 720.102, there be no waiting period or Agency approval required following submittal of a *NOA Form B* prior to commencement of manufacture or import of a formerly "inactive" substance. Once a company notifies the Agency, they should be considered compliant with the law and free to start commercial activities.

ACI recommends that U.S. EPA provide guidance for companies that have been or are engaging in mergers, acquisitions and divestitures. Acquisitions that may have or could take place after June 21, 2016 (including those that may occur during the 180-day reset reporting period) will not be able to submit notices for substances they wish to continue to manufacture or import as the acquiring company was not the manufacturer or importer during the 10-year lookback period. Likewise, companies who have divested businesses that may have manufactured or imported substances during the 10-year lookback may not have any intent to manufacture or import those substances in the future and, therefore, should not be obliged to report those substances.

As written, the proposed regulation suggests that a manufacturer or importer must report any substance that was in U.S. Commerce during the 10-year reporting period regardless of whether they are currently manufacturing or importing or intend to manufacture or import the substance. As stated in the paragraph above, this may not feasible or necessary. ACI recommends that EPA retain the statutes' proposed process for moving substances originally designated inactive to active when a person intends to manufacture or process the substance for non-exempt commercial purposes after the inventory has been reset (*NOA Form B*).

§ 710.29 Information required in the notification (b)(3)
In order to determine if a reportable chemical substance should be listed as active in U.S. Commerce within the last 10 years, reporting the specific date range in which a substance is manufactured or processed should not be necessary. Moreover, recreating the needed records to state the dates with accuracy and then to verify for purposes of the specific certification required might not be feasible. This is to be expected, given that the general TSCA recordkeeping obligations for most TSCA regulations do not extend beyond five years. The lookback period is set by statute; date range for reporting is not. To ease U.S. EPA's data collection burden without compromising the information necessary to determine the TSCA *active* inventory, ACI

recommends that U.S. EPA make the following modifications to Part II – Activity Information on the proposed *NOA Form A*:

1. Combine the categories "Domestically Manufactured" and "Imported" into one category, thereby simplifying the form to include only two options for type of commercial activity ("Domestically Manufactured/Imported" and "Processed").
2. Remove the "Date Range" fields.
3. Add a check box to identify "active" substances.

Modifying the NOA Form A as such will significantly reduce the effort required to both categorize substances in terms of manufacture versus input, as well as to determine date ranges of manufacture and import. Even without date ranges, the U.S. EPA will be able to both collect the list of substances manufactured/imported or processed within the last ten years as per the statute, and obtain the information necessary to establish an "active" list.

§ 710.30 When to submit notifications

ACI recommends that U.S. EPA allow for a non-punitive correction process for manufacturers and importers beyond the initial 180-day reporting period. Supply chain interactions will be a necessity during the Inventory reset process whereby processors will seek to ensure their substances are on the active Inventory. Similarly, processors should be allocated 180 days from the day the final active Inventory is published to correct or supplement substances they understand to be currently in U.S. Commerce.

Conclusion

ACI appreciates U.S. EPA's efforts to draft a proposed rule that is practical and limited in scope. There are a few sections, as noted above, that could be strengthened with more precise language, including some changes that will provide the information U.S. EPA needs with less burden on the manufacturers. ACI would be glad to discuss these recommendations and to work collaboratively on their implementation in a way that will result in a favorable outcome for all parties concerned.

Please contact me by phone at 202.662.2513 or by e-mail at kstanton@cleaninginstitute.org.

Sincerely,

Kathleen Stanton
Senior Director, Technical & Regulatory Affairs