Before the United States
Environmental Protection Agency

TSCA Inventory Notification
(Active-Inactive) Requirements
(Docket EPA-HQ-OPPT-2016-0426)

Comments of the Chemical Users Coalition

The U.S. Environmental Protection Agency recently issued for comment a proposed rule under Section 8(b) of the Toxic Substances Control Act ("TSCA"), at 82 Fed. Reg. 4255 (January 13, 2017), which would require notification for existing non-exempt chemical substances that are "active" in U.S. commerce. (Hereinafter, the "Inventory Reset Rule".) This proposed rule raises important precedential issues for the TSCA program, as modified by the Frank R. Lautenberg Chemical Safety for the 21st Century Act ("LCSA"). The Chemical Users Coalition ("CUC") appreciates the opportunity to provide comments concerning those issues.

CUC is an association of companies from diverse industries that are interested in chemical management policy from the perspective of those who use, rather than manufacture, chemical substances.[1] CUC believes in the importance of aligning protection of health and the environment with the pursuit of technological innovation, two goals that can and must be made compatible if our society is to achieve sustainable economic development. Aligning these goals is particularly important in the area of chemical management policy, which necessarily addresses how core technologies and products should be adapted to address emerging information about health and environmental risk.

CUC supported passage of the Frank R. Lautenberg Chemical Safety Act ("LCSA") and has a strong, continuing interest in implementation of the new law to assure that it results in an effective and efficient TSCA program. In commenting on the Inventory Reset Rule, CUC urges EPA to maintain flexibility for the wide, and diverse, set of parties who will be reporting under this rule. Such an approach will best advance the overall purpose of the rule – to identify what non-exempt chemical substances are "active" under the statutory definition of that term. We appreciate the steps that EPA is taking in the rule (e.g., the two-step reporting sequence set forth in §710.30(a)[2]) to create a practical and efficient process for obtaining the best information. In these comments, CUC asks EPA to clarify some interpretive issues that have arisen in our review of the proposed rule and

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[1] The members of CUC are Intel Corporation, Procter & Gamble Company, American Honda Motor Corporation, Lockheed Martin Corporation, HP Incorporated, IBM Company, Boeing Company, General Electric Company, and Airbus Americas S.A.S.

[2] All citations are from proposed 40 CFR Part 710.

makes recommendations that would improve flexibility in the process and thereby improve the quality of the information.

1. Content of Notification: Time Period for Manufacture or Processing During the Lookback Period

Proposed §710.29(b)(3) indicates that a notification filed for the lookback period must include the "first date and last date" that the substance was manufactured for TSCA purposes. This information is not required by the statute, and it is not essential information under the "active substance" definition. An "active substance" is a substance that has been manufactured or processed for a non-exempt commercial purpose "during the 10-year period ending on the day before June 22, 2016." The inquiry necessary to implement this provision poses a "Yes/No" question for the report submitters. The answer will be the same regardless of how long the substance may be manufactured or processed during that period.

To undertake the further inquiry necessary to identify the dates for which a chemical was manufactured or processed over a 10-year period can be a substantial burden for companies to investigate. Particularly for larger, multi-facility companies this can be a substantial undertaking, involving reviews of detailed plant by plant records. The task is further complicated by the fact that many companies may have engaged in significant corporate mergers, dispositions or acquisitions over a ten-year period.

CUC recognizes that, under this proposal, a reporter need only include information that is "known to or reasonably ascertainable" by the reporter. That standard, however, is inherently ambiguous under the TSCA regulations, and has been the subject of multiple requests for clarification over time.[3] More significantly, CUC does not believe that reporting the dates of manufacture or processing serves any larger purpose for clarifying the much simpler question of whether a chemical substance was manufactured or processed at any time during the lookback period, whether that be for 10 years or one day.

EPA's justification for reporting the "date range" information is that it should "reduce the likelihood of receiving erroneous notices (e.g., notices regarding commercial activity outside the lookback period), to support EPA's capacity to inquire into the accuracy of activity notices, and thus to increase the reliability of commercial activity designations on the TSCA Inventory."[4] CUC does not agree with this conclusion. Other steps that are included in the rule are fully sufficient to ensure that companies will base their conclusion that a substance is "active" on reliable information. Specifically, the certification statement required at §710.29(d)(5), which is quite specific, and the recordkeeping requirements of §710.35 provide strong assurances that companies will investigate information about their supply chain with the rigor necessary to meet the "known to or reasonably ascertainable" standard. In this context, the "data range"

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[3] Later in these comments, CUC will be seeking further clarifications of this regulatory standard.

[4] 82 Fed. Reg. 4255 (January 13, 2017) ("FR Notice"), at 4260.

information obligation is unnecessary for its intended objective, serves no clear statutory purpose, and thus is an unwarranted reporting burden.

2. Deadlines: Effect on Right to Manufacture Inventory Chemicals

Some members of the regulated community have identified a concern with the new statutory language in Section 8(b)(5)(B)(i), which states that a person who intends to manufacture or process an inactive substance "shall notify the Administrator before the date on which the inactive substance is manufactured or processed." The interpretive question that has been raised is whether this language puts a condition on further manufacture or processing of the substance or just articulates the timing of the notification obligation. It would be helpful for EPA to confirm its understanding of this language.

CUC views this language as addressing the timing of notification, and thus it is only relevant to the reporting obligations set forth in Section 8(b). It does not affect the underlying rights of companies regarding chemical substances that are on the Inventory or are otherwise exempt from the Inventory. Those rights are established by other sections of the TSCA statutory framework.

The central premise of TSCA, which was not changed by the LCSA, is that chemical substances on the Inventory, or otherwise exempt from the Inventory, are generally authorized to be manufactured, imported, processed, distributed, or used in the United States. This right to operate may be restricted through risk management actions taken under Section 5 or 6 of the statute. In addition, information reporting obligations under Section 8 may apply to Inventory chemicals, and those obligations may be separately enforceable. Section 8 reporting requirements, however, are not intended to place conditions on the right to operate, which accompanies the Inventory status of a substance.

This distinction is made clear in the statutory language underlying this Inventory Reset rule. Section 8(b)(4)(A)(iv) indicates that no chemical substance may be removed from the TSCA Inventory by reason of implementation of the Inventory Reset rules. Instead, these rules create distinct reporting requirements that may be enforced on their own terms under the general provisions of the statute. In that context, the language of Section 8(b)(5)(B)(i) identifies when notification is due for a substance that is moving from inactive to active status on the Inventory. Companies seeking to change the status of a substance from inactive to active status must adhere to that deadline. If they do not do so, they would have violated a reporting obligation and could face a penalty related to that obligation.

It should be noted that this interpretation is fully consistent with the statutory language of TSCA taken as a whole. Where the statute places limits on the right to operate, it says so explicitly. Specifically, Section 6(a) authorizes EPA to regulate manufacture, processing, distribution, use or disposal of a chemical substance to the extent necessary to address an unreasonable risk. The language of Section 5(a), which is even more relevant to the Inventory status of a chemical substance, makes it clear that no person "may manufacture

a new chemical substance" (i.e., a substance not on the TSCA Inventory) until the substance has been reviewed under the Section 5 new chemical program. Similarly, Section 5(a)(1) provides that a person subject to a Significant New Use Rule issued under Section 5(a)(2) may not "manufacture or process" the chemical substance subject to such a rule, unless the terms of such a rule have been met. Neither the language of Section 8(b)(5)(B)(i), nor the other Inventory Reset Rule provisions in Section 8, explicitly restrict the right to manufacture, import, process, distribute or use a chemical substance.

3. Deadlines: Thirty-day Limit on Forward-looking Reporting

Proposed §710.30(b), which address notification for a substance moving from inactive to active status, indicates that the notification must be submitted "before a person manufactures or processes the inactive substance, but not more than 30 days prior to the actual date of manufacturing or processing." CUC objects to the 30-day limitation in this provision.

This proposed provision properly recognizes that there is no need to set a deadline that creates a waiting period between notification and the commencement of manufacture or processing, particularly since the substances covered by this reporting obligation are already on the Inventory and would not be subject to any additional substantive review as part of identifying them as active substances. Thus the reporting obligation is met if the notification occurs "before", even a few days before, the date of manufacture or processing.

At the same time, EPA is proposing to limit companies from being diligent and filing their notifications when a date for initiating manufacture or processing has been set, which could occur more than 30 days before actual manufacture or processing occurs. EPA should not attempt to restrict business flexibility in this area. Notifications that occur prior to the 30-day restriction just provide prompt notice of a change in a chemical's status, which only serves statutory purposes. Certainly industry recognizes that the other required actions that are triggered by notification (e.g., the Section 8(b)(5)(B)(ii)(II) 30-day deadline for substantiation on CBI claims) would apply. Companies should be allowed the flexibility to manage those matters in a way that complies with the law and aligns with business planning objectives.

In the preamble to the proposed rule, EPA presents a rationale for the 30-day limit on notification that is "based on EPA's experience with Premanufacture Notices (PMNs)"[5]. This experience has apparently led EPA to the view that business, technical and unforeseen circumstances "may delay a company's plans to commercialize."[6] EPA concludes from those views that "a commercial activity notice reflects a more tentative or provisional intent to manufacture or process if it is submitted more than 30 days prior to

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[5] FR Notice, at 4260.

[6] Id.

the actual date of manufacturing or processing."[7] This is a sweeping conclusion that is not supported by any specific facts in the record. Moreover, it is drawn from an experience with new chemicals, many of which do not have established markets at the time the PMN process is complete. In the case of an inactive substance moving to active status, it may well be the case that a company has decided to revive a chemical application for which the use and the customer base is quite well-understood, and there may even be existing stocks of the substance available on hand. More generally, EPA's rationale is imposing a simplistic assumption on a set of diverse manufacturers and processors who have very different business dynamics and planning cycles.

It is also worth noting that the rationale offered in the preamble of this proposal is logically inconsistent with EPA's position on business planning horizons put forth in its reporting rule for nanoscale chemical substances.[8] In that rulemaking, and the final rule for those substances, EPA indicated that companies should be able to anticipate their date of actual manufacture or processing with sufficient precision to provide EPA with notification 135 days ahead of time. Yet in this proposed rule, EPA is saying that companies are unlikely to know such a date with any confidence until they are less than a month away from initiation of manufacture or processing.

The absence of a relevant record on this subject, coupled with the clear inconsistency with EPA's past statements on these matters, indicate that the subject of likely industry planning horizons is not an area that the Agency should attempt to regulate in the Inventory Reset rule. EPA should adhere to the statutory requirement that notification regarding an inactive substance moving to active status must occur "before" manufacture or processing of that substance begins, and remove the 30-day limit on when notification can be submitted.

4. Reporting at the Corporate or Facility Level Should Be Allowed

CUC is fully supportive of EPA efforts in the rule to design an efficient, flexible reporting framework that allows key actors to have input in identifying active substances. The two-stage reporting framework in §710.30 and the provision for reporting by co-manufacturers and co-processors in §710.33 are examples of this approach. CUC recommends that a similar approach be taken for reporting by individual corporations.

Some corporations would prefer to comply with its notification obligations with a single filing for the whole corporation. Other companies, particularly those with a very large set

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[7] Id.

[8] EPA recently issued a rule under TSCA Section 8 requiring reporting for certain chemical substances manufactured or processed at the nanoscale. One of the elements of the rule is a requirement for manufacturers and processors to file their reports 135 days "before manufacturing or processing" a regulated nanoscale substance. EPA justified this obligation "based on EPA's experience with the Premanufacture Notice (PMN) program." EPA concluded that "companies have the requisite intent to manufacture or process at least 135 days before manufacturing or processing will begin, and the rule requires reporting based upon this presumed intent." 82 Fed. Reg. 3641 (January 12, 2017), at 3649.

of U.S. facilities or a highly decentralized corporate structure, would prefer to allow for reporting by corporate business units or individual facilities. There would also be some companies who would like to pursue a mix of those approaches to accomplish the reporting in the most efficient way.

These differences in approach reflect the diversity of the reporting community. In some cases there are corporate circumstances (e.g., recent acquisition or mergers, joint venture arrangements) that make it reasonable for different sub-units of a larger corporation to report on different families of chemical substances, due to their deeper understanding of the relevant chemistry. In other cases, the sheer number of distinct facilities within a large corporation makes reporting at a facility level more realistic, avoiding the high transactions costs of rolling up information from hundreds of sites into a single report. There also may be practical advantages to such an approach for EPA from a data management perspective. Some of our members have had experiences with EPA's electronic reporting system suggesting that it will be difficult for the Agency to process the large electronic files that would be generated if a large multi-facility corporation had to file a single report for the whole corporation.

We note that the statute does not necessarily preclude this kind of flexible reporting, nor does the proposed rule as written. The reporting obligation is imposed, under §710.25, on "persons" as defined in the rule, which would include "corporations". At the same time, the rule does not preclude a corporation from meeting its reporting obligations by submitting information from multiple business units or facilities within the corporation.

Certainly any flexibility regarding who may submit a corporation's report would need to assure that the relevant corporate entity engaged in the TSCA-related manufacture and reporting has fully met its statutory obligations. In addition, the responsible corporate entity would be responsible if one of the reporting entities within the corporation did not complete its reporting responsibility, consistent with the principle articulated for co-manufacturers or co-processors in §710.33(b).

5. Clarification of "Known or Reasonably Ascertainable" Standard

One of the primary challenges facing reporters under the Inventory Reset Rule will be determining what substances have been manufactured or processed going back to June 21, 2006, as required by statute. EPA's primary response to stakeholders who have expressed concern about these challenges is that the Agency expects reporters to submit information "to the extent that such information is known or reasonably ascertainable." Thus, it is essential for the universe of reporting entities to have a clear sense of how EPA interprets the term "known or reasonably ascertainable" information.

This is not a new issue for EPA, as this term has been used in multiple TSCA regulations over the years. In particular, the scope of inquiry required by these terms was a major issue in the Chemical Data Reporting ("CDR") rule. In the preamble to that final rule, and in subsequent interpretive guidance, EPA has explained its perspective on the level of

inquiry that companies should undertake to meet the "known or reasonably ascertainable information" obligation.[9]

As a starting point, EPA should clarify whether that CDR reporting guidance can be used as guidance for purposes of the Inventory Reset Rule, including any clarifications about guidance that is not relevant. In particular, CUC supports the principle established in the CDR context that it is not necessary for companies to initiate new surveys of the relevant universe of parties, which would primarily be suppliers for the Inventory Reset Rule, in order to comply with the rule. This would mean that companies could focus on information in their possession to identify chemical substances in their supply chain. We ask EPA to confirm this understanding.

As a more specific question, CUC members would like to know what obligations a company has for a facility or business that was sold during the lookback period. In many cases, the selling company would not retain records on chemical usage for the business or facility conveyed to the buyer, and the employees who worked in the sold business or facility would also not remain with the selling company. Where the selling company does not have relevant information that would allow it to support identification of active substances for the sold business or facility, it is reasonable to assume that reporting for sold businesses or facilities would not be required. We ask that EPA confirm this understanding.

6. EPA should add additional features to the supplemental notification period provided for in §710.30(a)(2)

CUC supports EPA's proposal, under §710.30(a)(2), to allow processors an opportunity to supplement the active substance notifications submitted by manufacturers under §710.30(a)(1). We recommend a few additions to this provision that would enhance its effectiveness in giving EPA the best available information about active substances.

a. The role of chemical users

As drafted, §710.30(a)(2) allows only processors to provide additional notifications during the specified submission period. In fact, there may be situations where chemical users would also have useful information about chemicals that have been used over the previous ten years. There are several scenarios where this could occur, but chemical import situations may present the most likely circumstances.

In many cases, importers of record for TSCA purposes may be brokers or related transportation companies that do not have substantial information about the chemical names of the substances in the products they import. It is also possible that the importer of record has gone out of business and is not available as a

[9] *See* 76 Fed. Reg. 50816 (August 16, 2011). Specifically, EPA provides guidance on the inquiry needed to identify "known or reasonably ascertainable information" at pages 50829-30 and 50848-9 in the preamble to the final regulation.

practical matter for TSCA reporting. In those situations, it is more likely that the chemical processor or user in the U.S. is the entity most likely to know or discover the identity of the chemical substance.

EPA is not compelled by the statute to limit this reporting opportunity to chemical processors. While EPA cannot mandate Inventory Reset reporting for chemical users, it is certainly permitted to allow users to report, in the interest of developing a more accurate list of active substances. Opening reporting to chemical users is particularly compelling given the nuanced distinctions between what constitutes chemical "processing" and "use".

As an example, EPA guidance indicates that when an ink, which is a chemical mixture under TSCA, is applied to a shipping package, the chemicals in the pigment within the ink are "processed" because they stay with the package, while the solvents present in the ink are "used" because they are released from the ink as part of the printing process. In the context of the Inventory Reset rule as currently drafted, this would mean that a company involved in applying the ink to the package could (as processors) report the substances in the ink pigments but could not (as users) report the substances in the ink solvents. This kind of distinction does not make any practical sense in the context of the Inventory Reset rule and its purposes. Accordingly the supplemental reporting opportunity afforded to processors under §710.30(a)(2) should include both chemical processors and users.

b. Supplemental reporting by manufacturers

As with the situation with chemical users, it is also possible that chemical manufacturers, who have reported within the first 180 days under §710.30(a)(1), may learn additional information from their supply chain that would allow them to refine their report under the "known or reasonably ascertainable information" standard. This scenario would not necessarily be a non-compliance situation for the manufacturer, but could just be a situation where additional information comes to light from suppliers.

In the interest of getting the best available information on active substances, EPA should allow chemical manufacturers to supplement their reports during the submission period that is allowed under §710.30(a)(2).

c. Adjusting the submission period under §710.30(a)(2) based on the release date of the first draft of the Active Substances List

Under the proposed version of §710.30(a)(2), the submission period for processor reporting is 360 days after the final Inventory Reset Rule is issued. The premise of this timeline is that EPA will have issued its draft of the Active Substances List, based on manufacturer reporting, with enough time for processors to review that list and then identify any additional active substances.

If EPA is prompt in issuing the draft Active Substances List, this timeline would work. If EPA is not able, for whatever reason, to issue the draft of the Active Substances List as quickly as it plans, there may not be enough time for processors (or users) to identify and file submissions on additional active substances. CUC recommends that EPA add an additional, contingent element to the submission deadline to account for this possibility. Specifically we recommend that the deadline be expressed as "[360 days after the date on which the final rule is published in the Federal Register] or at least 90 days after the date on which EPA issues its draft of the Active Substances List in response to completed manufacturer reporting under §710.30(a)(1), whichever date is shorter." Please note that the following recommendation for real-time updating of the Active Substances List is also a critical step to take in order to make the 90-day minimum deadline a practical opportunity.

d. Real-time updating of Active Substances List

Both for purposes of manufacturer reporting under §710.30(a)(1) and processor (and user) reporting under §710.30(a)(2),, it would be useful for notification reporters to have on-line access to EPA's draft Active Substances List as the Agency receives information and updates that list, ideally on a weekly basis. If EPA could provide a real-time updated list, the entire process would be improved, especially if EPA clarifies that once a substance has been reported as "active", no one else needs to report it. That would expedite the process and reduce the likelihood that the §710.30(a)(2) submission period would need to be extended, as discussed above. It would also reduce substantially the number of duplicative notifications that are likely to be filed under EPA's current plan for sharing what it learns from the initial round of manufacturer reporting.

7. EPA should exercise enforcement discretion regarding chemical identification information that may be missed during the lookback period

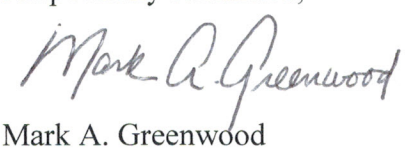
As noted previously, the overall purpose of this proposed rule is to identify the substances that are "active" under the statutory definition of that term. Manufacturers, importers, processors and users have a clear incentive to report fully the substances that they manufacture, import, process and use in order to have them placed on the Active list.

In some circumstances, it will be easy for an entity to identify substances that should be placed on the active list (e.g., a company that is manufacturing Chemical X for sale to downstream users easily can report Chemical X). In other circumstances, it will be difficult for an entity to identify all of the substances that it or its suppliers is (are) manufacturing, importing, processing or using (e.g., a company that is importing a formulation for which complete information on chemical composition is not available). In such circumstances, even the most diligent reporter might learn that it is manufacturing processing, importing or using a substance after the statutory deadline for reporting has

passed. Companies that submit a notice of activity to EPA after learning of the substance might be subject to a penalty for late reporting.

The possibility of a penalty could cause some entities NOT to submit a Notice of Activity form to EPA for substances identified after the reporting deadline has passed. To remove that disincentive to reporting, EPA should advise the regulated community that EPA will not seek penalties for reporting substances after the deadline so long as the reporting entity can demonstrate that it submitted the Notice of Activity promptly upon learning of the chemical substance. That exercise of enforcement discretion will help ensure that the Active Inventory is as complete as possible.

Respectfully submitted,



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On behalf of the Chemical Users Coalition