



Derek D. Swick, PHD, MPP
Manager

Regulatory and Scientific Affairs

1220 L Street, NW
Washington, DC 20005-4070
USA
Telephone 202-682-8341
Email swickd@api.org
www.api.org

September 20, 2016

Andrea Cherepy
Office of Pollution Prevention and Toxics
U.S. Environmental Protection Agency
Via Email: cherepy.andrea@epa.gov

RE: **TSCA section 8(b)(4) Inventory “reset”**

Dear Ms. Cherepy:

The American Petroleum Institute (API) writes regarding implementation of TSCA section 8(b)(4) as amended by the Frank R. Lautenberg Chemical Safety for the 21st Century Act (LCSA). The LCSA directs the U.S. Environmental Protection Agency (EPA) to issue a rule to require manufactures and possibly processors to report chemical substances on the TSCA Inventory that they manufactured or processed during the 10-year period prior to the date of enactment—also known as the TSCA Inventory “reset.”

API represents over 640 oil and natural gas companies, leaders of a technology-driven industry that supplies most of America’s energy and supports more than 9.8 million jobs and eight percent of the U.S. economy. API members include producers, refiners, suppliers, pipeline operators, and marine transporters of oil and natural gas, as well as service and supply companies that support all segments of the industry. Many of our member companies are likely to be subject to the Inventory reset rule or at a minimum will need to assess applicability of the requirements.

Under amended TSCA section 8(b)(4), within one year of enactment, EPA by rule shall require manufacturers and may require processors to report each chemical substance on the TSCA Inventory that the manufacturer or processor, as applicable, has manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment. Chemicals for which notices are received are **active substances** and chemicals for which no notices are received are **inactive substances**. Any person who intends to manufacture or process for a nonexempt commercial purpose a chemical substance that is designated as an inactive substance will be required to notify EPA before the date on which the inactive substance is manufactured or processed.

It is very important that EPA implements the TSCA Inventory reset requirements in a manner that is efficient for the Agency and the regulated community, while meeting the statutory

purpose of the requirement. The purpose of the requirement is to designate active and inactive substances. In writing a proposed rule, EPA should think about how to accomplish this directly and should not venture into consideration of using the reporting for other purposes (e.g., gathering information beyond that required to designate active and inactive substances). API would like to offer the following ideas and recommendations regarding the TSCA Inventory reset and how it can be implemented effectively.

The rule should require only the information necessary to designate substances as active or inactive. This could be accomplished via a simple online portal, with CDR-reported chemicals as the starting point for the active list.

The information needed to fulfill the purpose of TSCA section 8(b)(4)-(6) is whether a chemical has been manufactured or processed for a nonexempt commercial purpose during the 10-year period ending on the day before the date of enactment of the LCSA. The information required to be reported should be limited to the information necessary to establish the active and inactive lists, i.e., the identity of the chemical manufactured. Additional information (e.g., production volumes, uses, etc.) should not be required.

EPA has the opportunity to design a simple and efficient system for resetting the Inventory. API recommends that EPA establish an online portal that would operate as follows. The portal would enable a company to indicate that it manufactured a chemical(s) on the TSCA Inventory during the applicable time period. That chemical would then be indicated as having active status. EPA would provide the in-progress list of active chemicals online, in real time as they are reported. Once a chemical is flagged as active, additional reports for the chemical need not be required.

By the time of the Inventory reset rule, EPA will have two relevant TSCA Chemical Data Reporting (CDR) data sets (2012 and 2016). Chemical substances reported in either of these CDR cycles meet the criteria for active substances. EPA should designate all substances reported in one or both of these CDR periods as active, and should not require any TSCA Inventory reset reporting for them. If EPA implements the online in-progress list as suggested above, the list of chemicals reported to CDR in 2012 and 2016 would be the starting point for it.

Reporting by processors should not be required.

For companies, the exercise of reviewing operations to identify chemicals manufactured (which includes imported) during a 10-year lookback period will be challenging. The effort would expand significantly if companies were also required to identify all chemicals processed—many more companies would be affected and the effort per company would increase substantially. Requiring processors to report for the Inventory reset is unnecessary, because requiring manufacturers (which includes importers) to report would encompass all chemicals in commerce,

which may be subsequently processed. Processor reporting should not be required because it is unnecessary and would impose significant unnecessary burden—on companies required to report, on companies that gather and review 10 years of data and then conclude they do not need to report, and on EPA to process the reports.

Processor reports simply are not needed to compile the lists of active and inactive substances. However, there may be reason for a processor to want to report, for instance if a company is processing a chemical that is vital to its business and wants to ensure that it is on the active list. For this reason, it would be reasonable to allow processors to report voluntarily.

API recommends that EPA take an approach similar to the reporting to establish the original TSCA Inventory. The original Inventory Reporting Regulations (40 CFR part 710) established a two-phased reporting scheme. During the first phase, manufacturers and importers of bulk chemicals were required to report, and EPA then published an initial Inventory based on those reports. During the second phase, a processor could voluntarily report a chemical if the manufacturer(s) had failed to do so.

The rule needs to include appropriate exemptions.

The reporting rule should include all exemptions currently in the premanufacture notification (PMN) regulations in 40 CFR Part 720, including exemptions for R&D substances, non-isolated intermediates, chemical substances imported as part of articles, impurities, certain byproducts, and substances specified in 40 CFR 720.30(h)(3) – (7). This is vital to ensure consistency with the regulations that have governed reporting for Inventory purposes for the entire history of the TSCA program.¹ Also, the rule should be clear that materials excluded from the definition of *chemical substance* (e.g., pesticides, food, drugs, devices, cosmetics) are not covered.

There should be no change to treatment of naturally occurring substances.

Naturally occurring substances were deemed in the initial Inventory reporting requirements to be automatically included in the TSCA Inventory. EPA should continue its longstanding treatment of naturally occurring substances by not requiring that they be reported, but considering them automatically included on the active list.

Nomenclature policies and interpretations need to be maintained.

EPA's almost 40 years of TSCA implementation has produced a body of policy and interpretation regarding chemical substance identification and nomenclature. During the Inventory reset, EPA should not contradict past guidance or interpretation. The need to preserve the way in which chemical substances have been identified under TSCA is emphasized in the

¹ These exemptions are also reflected in CDR regulations at 40 CFR Part 711.

LCSA.² Longstanding nomenclature for substances of Unknown or Variable Composition, Complex Reaction Products and Biological Materials (UVCB substances), such as petroleum process streams, must be maintained. The Inventory reset exercise should not involve any redefinition of existing TSCA Inventory listings.

EPA should consider a potential role for non-U.S. entities.

API recommends that EPA consider establishing a mechanism to enable a third party outside the U.S. to report a substance to the reset inventory without disclosing the chemical identity to their U.S. customer. This would be analogous to the Only Representative (OR) concept in the European Union.

EPA should use a new name for the reset Inventory.

API recommends calling the reset inventory something different from the “TSCA Inventory,” to distinguish the reset Inventory from the version prior to the reset. The distinction is necessary for a variety of purposes, such as knowing whether supplier-provided information is confirming that a product contains substances on the original inventory or the reset one.

No information currently claimed CBI should be disclosed unless and until EPA notifies the party that claimed CBI of the pending disclosure and provides an opportunity for substantiation.

In addition to setting out the reporting requirements that will in essence “reset” the TSCA Inventory, the LCSA includes provisions on related confidential business information (CBI). As with the current TSCA Inventory, the reset TSCA Inventory will have a confidential and a non-confidential portion. If a manufacturer or processor wants to maintain an existing confidentiality claim for specific chemical identity, the company will need to submit a notice of the request and substantiation for it. EPA will move any active chemical substance for which no request was received to the public portion of the Inventory.

It is important that EPA have a clear process for any disclosure of chemical identity for any chemical currently on the confidential portion of the Inventory, and that the process include ample safeguards for information that was previously claimed CBI and still may be legitimately CBI. No information currently claimed CBI should be disclosed unless and until EPA notifies the claiming party that claimed CBI of the pending disclosure and provides an opportunity for substantiation.

² Under TSCA section 8(b)(3) as amended by the LCSA, in carrying out section 8 reporting requirements, EPA shall maintain the use of Class 2 nomenclature in use on the date of enactment; maintain the use of the Soap and Detergent Association Nomenclature System; and treat the individual members of the categories of chemical substances identified by EPA as statutory mixtures, as defined in Inventory descriptions, as being included on the list.

The reporting process should include a clear and efficient mechanism for companies to ask questions and receive answers during the reporting period.

The Inventory reset reporting will be different than any existing TSCA requirement, and thus is bound to raise many questions. Given that the statute requires reporting within 180 days of the final rule, it is essential that there be a clear and quick way for EPA to receive and answer questions during the reporting period. EPA should ensure adequate staffing to resolve questions, and should share answers in real time with the public (subject to CBI protections where appropriate), in an online Q&A or similar format.

API appreciates that EPA is working diligently to fulfill the many obligations that it has under the LCSA. API hopes that the suggestions herein serve as constructive input. If you have any questions, please feel free to contact me.

Sincerely,

A handwritten signature in black ink, appearing to read "David A. ...". The signature is written in a cursive style with a large initial "D".