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NEWSLETTER

EPA Seeks Comments on TSCA Reform Inventory Notification Proposed Rule

March 2017

Product Stewardship and Sustainability Report

By June of this year EPA must finalize three separate rule packages that will set the ground rules for the agency's review of several thousand chemicals over the coming years and decades. These rules are mandated by 2016's Lautenberg Chemical Safety Act (Lautenberg), which substantially revised the Toxic Substances Control Act for the first time in nearly 40 years. These first three rules will implement the LCSA's mandate to (i) "reset" the TSCA Inventory to identify chemicals actually in use today; (ii) create the prioritization process by which EPA will choose chemicals for review; and (iii) create the risk evaluation process under which EPA will review the chosen chemicals. These proposed rules and areas for comment are discussed in the article on page one of this newsletter.

On January 13, 2017, EPA issued the first of these proposed rules, the "Inventory Reset" rule. The Inventory was initially published in 1979 and now lists 85,000+ chemicals, most of which have never been subject to a risk-based review. The purpose of this proposed Inventory Reset rule is to focus EPA's limited prioritization and risk evaluation resources only on chemicals that could potentially pose a risk to human health or the environment.

The proposed Inventory Reset rule would require chemical manufacturers, importers and, in certain cases, processors to submit electronic notifications to EPA to establish which chemicals on the TSCA Inventory are commercially "active" in the U.S. 15 U.S.C. § § 2607(b)(4) and (5) and 82 Fed. Reg. 4255. Comments on the proposed rule are due on or before March 14, 2017. EPA must finalize the rule by June 22, 2017.

Practice Areas

Environment & Product Regulation

Overview

For reportable chemicals, EPA is proposing to break the commercial activity notification obligations into two categories: "retrospective" and "forward-looking" activity notification, with each type reported on yet-to-be developed "Notice of Activity" (NOA) forms: Form A and Form B. These forms will require information on chemical identity, type of activity (manufacture, import or processing), dates of manufacture or processing, and whether existing confidential chemical identity claims are to be maintained.

Retrospective Commercial Activity Notices

Mandatory for manufacturers (a term which, under TSCA, includes importers), "retrospective" reporting on NOA Form A would establish which chemicals have been active and inactive in the recent past. But Lautenberg requires EPA to focus its energies by requiring retrospective notification only on chemicals manufactured between June 21, 2006 and June 21, 2016 (the "look back period"), which EPA has proposed.

EPA also is proposing to allow chemical processors to file "retrospective" reports on a voluntary basis. Processors might choose to do so as a protection, for example, in case all of a chemical's manufacturers fail to report their chemical(s) to EPA. This would preclude future forward-looking reporting and possible related business delays for the processor.

Manufacturers and importers would have 180 days after the final rule is published to file the retrospective NOA Form A. Processors would have 360 days. This provides processors additional time to assess manufacturer reporting and avoid unnecessary duplicate reporting. Inactive chemicals will remain on the Inventory and be designated as such, but EPA will not expend resources prioritizing and assessing them for risk.

Forward-Looking Commercial Activity Notices

Forward-looking commercial activity notification would provide a mechanism for future manufacturers or processors of inactive chemicals to re-establish them as active with EPA to avoid TSCA violations. Under Lautenberg, it is a violation to manufacture or process an inactive substance for a non-exempt commercial purpose without first notifying EPA. EPA is proposing to require manufacturers and processors to file prospective notices on NOA Form B. Once submitted, the chemical will be deemed "active," and the filing entity can begin manufacturing or importing as soon as the form is filed. To maintain the accuracy of this reporting, however, forward-looking notifications cannot be filed more than 30 days in advance of the date of actual manufacturing or processing.

Notification Exemptions

To ease burdens on industry, EPA is exempting from notification obligations and automatically declaring as active all non-confidential chemicals reported to EPA under the 2012 and 2016 TSCA Chemical Data Reporting (CDR) rules. However, confidential chemicals from these CDR reports will need to re-report to maintain confidential status.

EPA also is exempting from notification certain naturally occurring substances, chemicals produced in small quantities for R&D, chemicals imported as part of articles, and certain chemical categories described in 40 C. F.R. §§ 720.30(g) or (h). In addition, chemical substances added to the Inventory on or after June 22, 2016 through the New Chemicals pre-manufacture notice (PMN) process would be automatically designated as active.

Interim Substances List

Prior to publication of the final Inventory Notification Rule, EPA must issue an "interim" active substances list consisting of all chemicals reported under the TSCA 2012 CDR rule in order to assist industry to determine their notification obligations. That list later will be expanded after the 2016 CDR data becomes available.

How to Maintain Confidential Status

Finally, under the proposed rule, the confidential portion of the TSCA Inventory would continue to be maintained. Persons who wish to report chemical substances listed on the confidential portion of the TSCA Inventory would be required to report the chemical substances using a TSCA Accession Number and generic name.

Relatedly, however, the new rule also would substantially revise portions of the TSCA confidential business information (CBI) rules. If a company manufactures or imports a chemical that is currently on the confidential Inventory, and it wishes to maintain its confidential status, that request would have to be asserted in NOA Form A. If a chemical is identified as "active," but no manufacturer or processor requests on their NOA Form A to maintain the existing CBI claim for chemical identity, EPA would move the chemical to the non-confidential portion. However, manufacturer substantiation that the claim is valid would not be required at the time NOA Form A is submitted. Instead, that issue will be addressed in a substantiation rule to be proposed within one year of publishing the first compiled list of active chemicals.[1]

In contrast, requests to maintain existing CBI claims for a specific chemical identity on the forward looking NOA Form B will need to be substantiated not later than 30 days after submitting the NOA Form B or at the same time that NOA Form B is filed. The same set of questions used for NOA Form A will be required for NOA Form B.[2]

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[1] Nonetheless, a manufacturer can voluntarily substantiate chemical identity confidentiality claims up front with the NOA Form A submission by answering eleven questions that EPA has included in the current proposed rule. These questions seek to establish whether or not a chemical's identity is legitimately protected, and that the information is unavailable to the public through means other than the TSCA Inventory (*e.g.*, Can the substance be reverse engineered? Is it patented? Is its identity anywhere else in the public domain (*e.g.*, journals, promotional materials). *See* 40 C.F.R. § 710.37(a)(1)(iii).

[2] Certain other elements of NOA Forms A & B (other than chemical identity) can also be claimed as confidential but substantiation is required when NOA Form A or B is filed. Responses to the substantiation questions set forth at §710.37(b)(1) must be included with the submission.