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ALERT

Why Companies Need to Pay Attention to the TSCA Reset Exercise

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Starting in June 2017, the Environmental Protection Agency (EPA) is being asked to lead industry through an update of the Toxic Substances Control Act (TSCA) Chemical Substances Inventory (TSCA Inventory). EPA's proposal calls on companies to notify chemicals in U.S. commerce for the 10 year period prior to June 22, 2016. Manufacturers and importers must participate, and processors will be given the opportunity to do so.

By statute, EPA must finalize this rule by June 22, 2017. For docket information and to view comment submissions, click here.

As we approach the one year mark since TSCA was updated, the TSCA Inventory is about to receive a fresh new look. It remains the featured centerpiece for industrial chemical compliance. As long as a chemical substance is on the TSCA Inventory or exempt from having to be listed, it may be manufactured, imported, processed, distributed and used in U.S. commerce. If not, the chemical is subject to a risk-based review by EPA before it can be added to the TSCA Inventory. The TSCA Inventory establishes a shared right to operate so that any company in the U.S. may rely on a listing to commercialize a product.

Whether you manufacture, import, process, distribute or use a chemical substance on the TSCA Inventory, you will need to review your chemical substance portfolio to make sure that the ingredients important for your business are notified during this period. The remainder of this article discusses the requirements, areas highlighted in public comments on the proposal, and why it is important to comply.

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Environment & Product Regulation
Toxic Substances Control Act (TSCA)

A. How Reset Works

The 2016 amendments to TSCA included a provision to benchmark the number of chemical substances on the Inventory that are commercially active today. When the TSCA Inventory was initially published in 1979, chemicals were added without being subject to a risk-based review. The "Inventory Reset" exercise is designed to be a simple procedure that will lay the foundation for EPA to go on to evaluate their safety.

EPA has created a new form for companies to use during Inventory Reset. The "Notice of Activity" (NOA) Form A asks for information like chemical identity, type of activity (manufacture, import or processing), and dates of manufacture, import or processing, and calls on companies to re-assert their existing confidential chemical identity claims. Also, prior to issuing the final rule in June, EPA is supposed to publish an "interim" active substances list that consists of the chemicals reported during the 2012 and 2016 TSCA Chemical Data Reporting (CDR) periods. After that, manufacturers and importers will have 6 months from the time the final rule is published to file these forms, one per chemical. This timeframe is fixed by the statute. Processors can submit these reports for up to one year. In addition, a joint submission process is proposed to allow upstream suppliers to report directly on behalf of customers. The electronic reporting portal will be available for use by companies outside of the U.S. and it is easy to sign up.

Chemicals that are not notified remain on the Inventory. The statute provides clear direction to EPA that these inactive substances cannot be de-listed based on this exercise. Being designated as inactive ensures that EPA will not expend resources prioritizing and assessing them for risk. If a company wants to manufacture, import or process an inactive chemical, it will need to submit a different form, NOA Form B, to let EPA know that the chemical is commercially active. EPA is proposing that these notifications cannot be filed more than 30 days in advance of the date of actual manufacturing or processing as a means to ensure the accuracy of the reports.

At the end of this exercise, the TSCA Inventory will look quite different. Instead of having only two parts, a confidential and a public portion, the Inventory will have four sections: public/active, public/inactive, confidential/active, and confidential inactive. For chemicals whose identities are claimed as CBI, EPA will need to list a unique identifier, accession number, generic name, and, if applicable, the premanufacture notice case number for each chemical substance on the confidential portion of the Inventory. The new law requires generic names to be structurally descriptive, and many of the generic names appearing on the public portion of the Inventory today will need to be updated to meet the standard.

B. Exemptions

EPA is proposing to declare all non-confidential chemicals reported to EPA under the 2012 and 2016 TSCA CDR as active substances. These will not have to be re-reported. However, "interim active substances" with identities that are protected as confidential business information (CBI) need to be reported during Inventory Reset if companies wish to reassert confidential protection of the name.

Chemical substances added to the Inventory on or after June 22, 2016 automatically are designated as active chemicals and do not need to be reported again during Inventory Reset. In addition, the proposed rule includes included exemptions for naturally occurring substances, chemicals produced in small quantities for R&D, chemicals imported as part of articles, and chemical exempt from PMN reporting under 40 C.F.R. § § 720.30(g) or (h), such as impurities and non-commercial byproducts. However, there is no exemption for small quantities of an otherwise non-exempt chemical.

Section 8 of TSCA and the Paperwork Reduction Act include safeguards against duplicative reporting, yet this is exactly what the Reset provisions contemplate. This part of TSCA states that manufacturers and importers need to report each substance they have manufactured (imported) in the past ten years. As a result, when an NOA Form A report is submitted by one company, it does not relieve a competitor from having to report the same chemical. Neither does the language in section 8 provide direct relief to a company who no longer sells a chemical that it has manufactured or imported in the past ten years. It does not seem reasonable to require a company to locate information and report on a product that is no longer of commercial interest. Perhaps EPA will be able to offer guidance and exercise its discretion in these cases.

C. CBI claims

During Reset, keeping the identities for chemicals on the TSA Inventory confidential is not a given. CBI claims will need to be re-asserted and are going to be scrutinized by EPA. A company may substantiate its CBI claims when it files the NOA Form A, or wait to do so as part of a separate rule EPA will propose within a year of publishing the first compiled list of active chemicals. Otherwise, a chemical on the confidential portion of the TSCA Inventory stands to lose its CBI protection if it is reported as "active," without asserting CBI protection for the name. In that case, EPA is proposing to routinely remove those chemicals from the confidential portion of the TSCA Inventory without further notice or opportunity to comment.

Companies that want to make a CBI claim and substantiate it during Inventory Reset will have to respond to a set of eleven questions that 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.

In the future, requests to maintain existing CBI claims when activating an inactive chemical will require the use of a different form, NOA Form B, and will need to be substantiated no later than 30 days after filing. The same set of questions used for NOA Form A will be required for NOA Form B.

D. Areas of public comment

Comments submitted by the public were generally supportive of keeping the process simple as well as voluntary for processors, along the lines of what EPA proposed. Two areas to watch for in terms of their outcome are whether the information requirements in the form will change in response to comments, whether EPA will agree to engage in a dialogue about chemical name equivalency during the Reset process.

In terms of information requirements, EPA was urged to reconsider the need to provide a date range of commercial activity because many companies will not have 10 years of sales information due to their record retention policies or in the case of mergers and acquisitions when these records are not transferred to the current owner. Other commenters asked EPA to expand the informational value of these notices to include the sites of manufacture, import, and processing, and storage volume and locations.

Several comments addressed the current naming systems for chemicals and asked EPA to make equivalency determinations available during the Reset process when more than one TSCA Inventory name describes a chemical. Commenters on CBI protection recommended that EPA ensure that adequate notice is given prior to removing a chemical from the confidential portion of the Inventory and allow a final opportunity for substantiation.

Commenters also thought it would be helpful if EPA confirmed that substances that qualify for the polymer exemption, the export-only exemption, the low-volume exemption (LVE), or the low release and low exposure (LoREX) exemption are exempt from Reset reporting. Today, these substances do not need to be listed on the TSCA Inventory if these exemptions are used. However, in the case of some older listings (e.g., substances that qualify for the old polymer exemption), a Reset report could be needed.

E. Reset Considerations

When it comes to Inventory Reset, six months is all Congress has allowed so companies need to do the best they can in the time they have. Keep in mind that EPA is only requiring companies to report what is "known to or reasonably ascertainable." This includes information in the reporting company's possession or control, "plus all information that a reasonable person similarly situated might be expected to possess, control, or know." Regulatory compliance offers can use this standard, which is the same one used and interpreted by EPA for TSCA CDR reporting, to direct their information collection activities.

EPA generally expects a company's information collection effort, under the "known to" portion of the standard, to extend to the full scope of their organization. This may mean going beyond managerial or supervisory employees but it need not be exhaustive. In addition, the "reasonably ascertainable" portion of standard may necessitate some limited amount of inquiry outside the organization to fill gaps in knowledge. This is probably most true in the case of importers, who may find they need to work with their suppliers to collect the information they need to report.

What can companies do to start getting ready for this ten-year look-back? The sheer number of supply chain complexities are guaranteed to make Inventory Resent a challenging exercise. Companies should start working out what chemicals to report and who will report ingredients claimed as confidential. In putting together the list of chemicals that need to be reported, companies should be mindful that the reporting exemption proposed for substances already reported during the 2012 and 2016 CDR periods does not apply if the chemical is on the confidential portion of the Inventory.

Companies who have reporting obligations for byproducts with their own commercial value need to evaluate these activities closely. And although chemicals imported as part of an article does not need to be reported, this exemption could be lost if they are subsequently released when the article is repurposed or recycled. Moreover, in the future, processors will be in the same position as manufacturers and importers in having to submit an NOA Form B to activate an inactive chemical.

It remains to be seen how the need to report for Inventory Reset will intersect with the ability of companies to continue to manufacture, import, process and use substances that are listed on the TSCA Inventory. Congress gave EPA clear instructions that inactive chemicals should not be removed from the Inventory as a result of this exercise. Will failing to activate a chemical substance be grounds for a civil penalty for nonreporting or does it prevent a company from continuing to manufacture, import, or process a chemical substance on the Inventory altogether? This is uncharted territory. Prudent companies along the supply chain will surely want to have assurance from their suppliers that this obligation has been discharged.

If you have questions about your company's role and obligations, contact Martha Marrapese at 202-719-7156 or mmarrapese@wiley.law.