SQUIRE PATTON BOGGS

Environmental, Safety & Health
US EPA Issues TSCA Inventory Reset Rule

Overview

On June 22, 2017, as required by the amended Toxic Substances Control Act (TSCA), the US Environmental Protection Agency (US EPA) issued its rule to "reset" the TSCA Inventory. The rule requires every chemical manufacturer and importer to notify US EPA of each chemical substance it manufactured or imported for a non-exempt commercial purpose in the US during the 10-year period ending June 21, 2016 (the "lookback period"). Manufacturers and importers must provide this notification to US EPA within 180 days from the date on which the rule is formally published in the Federal Register. Each chemical substance for which US EPA receives such a notification will be designated as "active" on the TSCA Inventory.

The rule also gives chemical processors the option to report to US EPA any chemical substance they processed during the same lookback period, but they must do so within 420 days from the rule's Federal Register publication date. Processors are given an extended submission period to allow them to review a "draft" version of the revised Inventory that US EPA will issue approximately 60 days after the close of the 180-day reporting period for manufacturers and importers. Processors thus will have roughly 180 days after US EPA issues the draft revised Inventory to identify any chemical substances that manufacturers have failed to designate as "active" and submit notices to US EPA for the substances they processed during the lookback period, in order to keep such substances from being designated as inactive.

Any chemical substance not reported to US EPA by a manufacturer, importer or processor by the applicable deadline will be designated as "inactive" on the Inventory. Once the Inventory "reset" is finalized, no one may manufacture, import or process an inactive substance without giving US EPA prior notice not more than 90 days before the anticipated date of manufacturing, importing or processing.

Inventory Transition Period

While a company may not manufacture, import or process an inactive substance without giving prior notice to US EPA, the rule provides that a substance actually will not be designated as inactive on the TSCA Inventory until 90 days after US EPA has "identified" the substance for inactive designation. US EPA calls this 90-day time frame the Inventory "transition" period. To kick off the transition period, US EPA will publish the first version of the revised Inventory on its website "as soon as practicable after compilation." This version of the Inventory will be accompanied by a "signed action" that will "identify" chemical substances for inactive designation.

Because the inactive designation will not be "effective" at that point, companies may continue to manufacture, import or process a substance after it has been identified for inactive designation, but they must notify US EPA of their activity prior to the end of the transition period, when the substance is actually designated as inactive, in order to continue their activity. Otherwise, they will have to cease their activity at the end of the 90-day transition period, and not resume it until they have given notice to US EPA (after which US EPA will designate the substance as active).

Reporting Process and Content

Under the rule, all reports must be filed electronically through US EPA's CDX system, using forms that US EPA has developed.

For "retrospective" reporting (i.e., notifying US EPA of substances manufactured, imported or processed during the lookback period), companies must use Notice of Activity (NOA) Form A to submit the information. Companies will be able to select chemicals for reporting from a "pick list" in the CDX system. Non-confidential substances will be listed by the Chemical Abstracts (CA) Index name and Chemical Abstracts Service registry number (CASRN). Substances on the confidential portion of the Inventory will be listed by EPA accession numbers and generic names. Any company reporting a confidential substance that wishes to maintain the confidential business information (CBI) claim for the substance's chemical identity must indicate so on the NOA Form A. If the company does not do so, US EPA will designate the substance as active, but will list it on the public portion of the Inventory.

For "prospective" reporting – i.e., giving US EPA notice of intent to manufacture or import a substance and move it from the inactive list to the active list – companies must use NOA Form B. In addition to providing information about the company and the substance, NOA Form B requires a submitter to indicate the anticipated date when manufacturing, processing or importing of the substance will begin. A company intending to manufacture, import or process an inactive substance must submit NOA Form B no more than 90 days before the anticipated date of the activity. Similarly, as noted, any company that continues to manufacture, import or process a substance during the transition period after the substance has been identified for inactive designation (but before its formal designation as inactive) may submit NOA Form B to US EPA before the end of the 90-day transition period. Otherwise, the company must cease its activity until such time as it files NOA Form B.

Confidentiality Claims

Under the rule, any manufacturer, importer or processor may seek to maintain an existing CBI claim for the chemical identify of a substance on the confidential portion of the TSCA Inventory, regardless of whether of whether it had asserted the original CBI claim.

The rule allows companies submitting retrospective reports using NOA Form A to seek to maintain existing CBI claims for chemical identity without having to provide substantiation for the CBI claim. This is because the amended TSCA requires US EPA to review CBI claims for chemical identity for active chemicals within five years after the Inventory is reset. US EPA's review plan will include mandatory requirements for substantiating a CBI request for chemical identity reported in a NOA Form A and will specify when the substantiation must be provided to US EPA. A company may voluntarily provide "early" substantiation for the CBI claim when it submits NOA Form A, however, and would not have to do so later during US EPA's review process as long as the time period between the date of such early substantiation and the date established in US EPA's review plan is not more than five years. If a CBI claim is not asserted by a manufacturer, importer or processor, US EPA will move the substance from the confidential portion of the Inventory to the non-confidential one.

Any company wishing to maintain an existing CBI claim for a substance that was added to the confidential portion of the TSCA Inventory prior to June 22, 2016 must submit a NOA Form A themselves and advise US EPA that the CBI claim should be maintained. Even if a confidential substance is exempt from the retroactive reporting requirement because a Notice of Commencement (NOC) was submitted to US EPA for it during the lookback period, US EPA will not keep the substance on the confidential portion of the TSCA Inventory unless it receives a notice from a manufacturer, importer or processor specifically asserting that the CBI claim should be maintained. Moreover, even if a company is relying on a CDX receipt from another manufacturer, it must submit a notice asserting the CBI claim for the substance if it wishes to maintain the claim. Otherwise, it runs the risk that no one else might assert the CBI claim, and US EPA would designate the substance as active, but list it on the non-confidential portion of the Inventory.

Although substantiation is not required for CBI claims for chemical identity when a NOA Form A is submitted, companies must provide substantiation for a CBI claim that is made in retrospective submissions for any other information relating to the substance.

With regard to CBI claims asserted in prospective reporting using NOA Form B, the rule requires that substantiation for any such claims must be provided to US EPA within 30 days after the NOA Form B is submitted. If the CBI substantiation is not received within 30 days, US EPA will move the substance from the confidential portion of the TSCA Inventory to the public portion.

Withdrawing and Correcting Notices

The rule allows a manufacturer, importer or processor to withdraw its submitted NOA Form A at any time prior to the applicable deadline for submission (i.e., 180 days after the Federal Register publication date for manufacturers and importers and 420 days for processors). Relatedly, a manufacturer, importer or processor may correct an error in its NOA Form A by withdrawing the submission and submitting a new, corrected NOA Form A prior to the applicable deadline.

A company may not withdraw a NOA Form B, however, without US EPA's approval. Once US EPA receives the NOA Form B advising the agency of the company's intent to manufacture import or process an inactive substance, the agency will redesignate the substance as active. If US EPA has not yet redesignated the substance as active, the agency may allow the NOA Form B to be withdrawn and keep the substance designated as inactive. If US EPA already has designated the substance as active, however, it will not redesignate the substance back to inactive status.

Similarly, if US EPA has moved a substance from the confidential portion of the Inventory to the public portion based on a submitted NOA Form B, it will not revert the substance back to a CBI substance.

Exemptions from the Notice Requirement

Under the rule, certain substances do not have to be reported to US EPA for purposes of the Inventory reset, including:

- Substances that are generally excluded from Inventory reporting based on the low volume exemption, LoREX exemption, polymer exemption, test marketing exemption or R&D exemption.
- Naturally occurring substances.
- Substances that were already reported in response to the 2012 or 2016 Chemical Data Reporting (CDR). These substances will be automatically designated as active and will make up an "interim" list of active substances that US EPA will issue. (Note: A company must file a NOA Form A for any substance on the confidential portion of the Inventory if the company wishes to maintain the CBI claim.)
- Substances that were added to the Inventory during the lookback period pursuant to a Notice of Commencement (NOC) submitted to US EPA during that period.
- Substances added to the TSCA Inventory since June 22, 2016.

In addition to these exemptions, the rule provides that a manufacturer (including importers) is not required to submit a notice for a substance covered by the lookback period if the manufacturer has "evidence in the form of a CDX receipt" from another manufacturer showing that the other manufacturer submitted a notice to US EPA for the substance.

US EPA established this exemption in response to concerns expressed by stakeholders about duplicative reporting of substances. In the preamble to the rule, however, US EPA cautions that any manufacturer relying on the exemption "bears the risk" if the other manufacturer later withdraws its notice and the substance is subsequently designated as inactive. As noted, once a substance has been formally designated as inactive, a company cannot manufacture, import or process the substance until the company submits NOA Form B to US EPA.

Additionally, as noted, a company seeking to maintain an existing CBI claim for the chemical identity of a substance must submit a NOA Form A and assert the CBI claim themselves even if a company is relying on a CDX receipt from another manufacturer. Otherwise, they run the risk that other company did not assert the CBI claim or even that the other company might withdraw its submission entirely.

Next Steps

For more information about the TSCA Inventory Reset Rule or any other aspect of TSCA, please contact one of the individuals listed in this publication.

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