TSCA active substance reporting: Advice for importers and manufacturers

What do companies need to do to comply with the new 'inventory reset'?

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Amended section 8(b) of the Toxic Substances Control Act (TSCA) requires the EPA to designate all substances on the TSCA Chemical Substance Inventory as either 'active' or 'inactive' in US commerce. The EPA will then prioritise and conduct risk evaluations of the active substances under two new rules that implement amended section 6 of TSCA.

Meanwhile, to identify active substances, the EPA is now requiring importers and manufacturers and allowing (but not requiring) processors to report substances added to the inventory before 21 June 2006, that they imported, manufactured or processed for any non-exempt commercial purpose during a ten-year 'lookback period' from then until 21 June 2016.

The EPA published its new active substances reporting rule on 11 August and it took effect immediately. Importers' and manufacturers' mandatory reports are now due to be submitted to the EPA by 7 February 2018 and processors' voluntary reports are due to be submitted by 5 October 2018.

(The new rule also requires 'persons' to report inactive substances to the EPA before starting to import, manufacture or process them, but this requirement does not take effect until the agency has published final designations for every substance on the inventory. This will not happen until some time after the 5 October 2018 deadline: this article therefore focuses on the mandatory reporting that importers and manufacturers must do by 7 February 2018.)

If a company imported or manufactured inventory-listed chemical substances during the lookback period and had an appropriate system for complying with TSCA at the time, it should not encounter serious obstacles to complying with the new active substances reporting rule, because relevant import or manufacturing records in its possession or control will be substantially complete (barring accidents) and organised by substance. Nonetheless, the points below may simplify reporting even for well-prepared importers and manufacturers.

Corporations are people too

Only 'persons' are subject to active substances reporting. The new rule defines a 'person' to include 'any individual, firm, company, corporation, joint-venture, partnership, sole proprietorship, association, or any other business entity'.

Therefore, if a company imported or manufactured chemical substances during the lookback period, it is potentially subject to active substances reporting. Conversely, if neither the company nor any predecessor existed during the lookback period, then there was no 'person' who could have imported or manufactured anything at the time and it can avoid active substances reporting.

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If both a company and a predecessor imported or manufactured during the lookback period, the EPA directs them to January 2016 guidance for the Chemical Data Reporting (CDR) Rule to resolve any questions about how to report. This guidance also discusses scenarios in which

a company that did not exist during the lookback period and a company that did may be the same 'person' for reporting purposes, for example, when:
» a company simply changed its name;
» a company span off a division that continued the company's prior importation or manufacturing of specific chemical substances;
» two companies merged and either one survived or neither did and instead formed a new company; or
» one company acquired a unit of another company and both continued to exist.

Therefore, if a company did not exist during the lookback period but a predecessor did and either imported or manufactured chemical substances, management should consult with its in-house counsel to understand the transaction that created the company and determine whether it is a successor to the other company for reporting purposes.

Take inventory

When reviewing a company's imports or manufacturing of substances during the lookback period, it is possible to ignore substances that were never added to the inventory, because they are excluded from active substances reporting.

(One should keep in mind, however, that if the company has been importing or manufacturing any substance that is not on the inventory and was not relying on and complying fully with an appropriate exemption from the TSCA section 5 premanufacture notice requirement at all relevant times, there is a potential TSCA compliance problem and in-house counsel should be contacted immediately for assistance.)

It is not necessary to report substances that are imported or manufactured solely as substances excluded from TSCA

In addition, two further groups of substances can be ignored, because the EPA already has designated them as active in the 20 June 2017 publication of the inventory: those added to the inventory since 21 June 2006 (that is, during or after the lookback period) and 'interim active substances' reported to the EPA under the CDR Rule in 2012 or 2016. Accordingly, the focus should be exclusively on the substances shown in the latest publication of the inventory without active substance designations, because these were added to the inventory before 21 June 2006, are not interim active substances and, thus, are subject to reporting.

Companies' past mergers may affect their reporting requirements

Excuse you

Even if a company imported or manufactured a substance on the latest inventory without an active substance designation, the new rule contains many exclusions and exemptions. It is not necessary to report substances that are imported or manufactured solely as substances excluded from TSCA, notably:
» pesticides;
» tobacco and tobacco products;
» nuclear material;
» firearms and ammunition, including components; and
» food, food additives, drugs, cosmetics, and medical devices, including components in each case.

Naturally occurring substances also are excluded from reporting, so long as their manufacture and processing occurs only by limited means prescribed by the EPA. The agency has provided many reporting exemptions familiar to importers and manufacturers of new chemical substances:
» import of a substance as part of an article;
» manufacture of a substance as a non-isolated intermediate;
» import or manufacture of a substance solely for export (conditions apply) or for test marketing, in small quantities solely for R&D, as an impurity, or as a by-product with no or only limited commercial purposes; and
» import or manufacture of a substance that resulted from a chemical reaction described in 40 CFR § 720.30(h)(3)-(7) (use with care).

The EPA does not exempt any substance imported or manufactured during the lookback period under the polymer exemption, the Polaroid exemption, the low volume exemption, or the low releases and low exposures exemption. However, if the substance is not on the latest inventory or is listed with an active substance designation, then it is excluded from active substances reporting anyway.

Lastly, there is no need to report a substance if acceptable documentation is available to show that the EPA received a report from another person for the same substance. This may occur, for example, when companies in a trade association or consortium agree that one member will report a substance for everyone.

Know what you know

There is also no need to report a substance to the EPA if any importation or manufacture of the substance during the lookback period is not 'known to or reasonably ascertainable by' the company. However, making this determination can be tricky. Basically, this definition applies if the information is:
» in the company's possession or control; or
» is information that a similarly situated reasonable company would know.

Information in a company's possession and control includes information possessed or controlled by other persons: any subsidiary, partnership in which the company is a general partner, parent company, or company or partnership that the parent company owns or controls.

Therefore, the EPA can hold a company responsible for knowing about relevant importation and manufacturing records possessed or controlled by any subsidiary,

parent company or corporate sibling that it has. Information in the company's possession and control also includes information in the following 'locations':

» the company's own files, including those maintained by employees in the course of their employment;

» commercially available databases to which the company has purchased access; and

» files maintained in the course of employment by agents of the company who are associated with research, development, test marketing or commercial marketing of the chemical substance in question.

Thus, what information is in the company's possession or control is reasonably clear. However, whether information *not* in its possession or control is nonetheless 'information that a similarly situated reasonable company would know' is unclear.

The EPA says that it is appropriate to construe the term 'based on the totality of pertinent factors' (which is unhelpful) and that '[p]rior loss of records consistent with document retention policies and … other individual factors … could be pertinent in construing what information is known or reasonably ascertainable' (ditto).

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In addition, the EPA directs companies to guidance issued for the 2016 CDR Rule, but the two guidance documents that the EPA specifically references do not suggest what a company should do when import or manufacturing records are missing for any portion of the lookback period. Therefore, companies may be unable to decide what, if anything, to do in the case of missing records.

Keep a secret

TSCA requires the EPA to move any active substance from the confidential portion of the inventory to the public portion, if no person asks the agency to keep the chemical identity of the substance confidential.

The TSCA inventory includes a confidential portion as well as a public portion

Therefore, if a company imported or manufactured a chemical substance added to the confidential portion of the inventory at any time before 22 June 2016, if it does not know whether anyone else will report the substance and asks the EPA to preserve its confidential identity, and if it wants to ensure that the substance's identity remains confidential, it will need to report the confidential substance to the agency under the new rule, even if the company would otherwise be excused from reporting the substance, for example, because the EPA already has designated it as active in the latest inventory or the substance was imported or manufactured for an exempt purpose.

There is no need to substantiate a claim of confidentiality for the substance's identity in the report to the EPA. Instead, the agency will conduct a separate rulemaking under which the company will do this. Until this is done and the EPA has reviewed it under the future rulemaking, the substance will remain on the confidential portion of the inventory.

Other people's secrets

If a company manufactures substances or imports them from affiliates who manufacture them, it will usually know the substances' identities. If the company imports substances from unrelated suppliers, however, it will often encounter trade secret claims for their identities. Companies import trade secret substances under procedures that may or may not ensure TSCA compliance.

To facilitate the reporting of trade secret substances, the EPA gives importers two options. If such a substance is on the confidential portion of the inventory, the agency's online reporting form contains a 'pick list' that will allow the importer to identify the substance by the EPA accession number and corresponding generic name, which the supplier should be able to provide and has no reason to withhold.

If the trade secret substance is on the public portion of the inventory, however, then the supplier cannot give the importer an EPA accession number or the substance's identity while keeping it secret. In this case, the importer can make a joint submission in which it provides the information available to it and invites the supplier to separately submit the confidential substance's identity directly to the EPA. The importer fulfils its obligation by submitting its portion of the joint submission regardless of what the supplier does.

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