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NEWSLETTER

Are You Sure Your Chemical Is on the TSCA Inventory?

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The Toxic Substances Control Act (TSCA) generally requires companies planning to manufacture or import a chemical substance into the United States to confirm that the substance is included on the Chemical Substance Inventory (Inventory) the U.S. Environmental Protection Agency (EPA) has created. (Pesticide and U.S. Food & Drug Administration products are separately regulated, however, and not subject to this requirement.) EPA makes the Inventory available to the public online, and it is a very useful tool. It is also important to recognize that tool's limitations, however, and that other review steps may be necessary in a particular situation. This article flags several of them.

Background

The TSCA Inventory is a list of more than 80,000 chemicals in commercial production and use in the United States. If a chemical is not on it, a company generally must file a premanufacture notice (PMN) with EPA 90 days prior to commercial production. In response to PMNs, EPA conducts a review to determine possible adverse human health and environmental effects of the "new" chemical. If that review shows acceptable results, and after the PMN submitter commences commercial manufacture and notifies EPA of that fact, EPA places the chemical on the Inventory.[1]

If the review shows concerns, however, the agency can place enforceable restrictions on the chemical. These may include workplace air exposure limits, mandatory worker use of respirators, or prohibitions on water releases, among many others. (EPA also has the authority to completely prohibit production of a chemical, but this is unusual. Instead, companies may voluntarily decide against manufacturing a substance if the requirements of a 5(e) consent order are too onerous.)

The same restrictions typically are applied to any subsequent manufacturers by the agency's promulgation of a Significant New Use Rule (SNUR). The restrictions imposed on the submitter typically are embodied in a consent order issued under authority of TSCA Section 5(e). Any TSCA rules applicable to a substance are indicated on the Inventory.

Looking at Publicly Available Information May Not Be Enough

The Inventory and Federal Register notices summarizing PMN submissions, notices of commencement, and SNURs are vital and useful indicators about competitors' activities and regulatory controls that may apply to one's own company if it produces the same or similar chemicals. But searching EPA's Chemical Substance Inventory is more complicated than one might guess.

First of all, there are two sections to the Inventory: 1.) the Public Inventory, in which a chemical's composition is fully disclosed (CAS number, complete chemical name, chemical formula), and 2.) the Confidential Inventory, in which no CAS number is provided and only a generic name is included. The exact chemical composition of the substance cannot be discerned from this generic name. Chemicals are placed on the Confidential Inventory when a company can justify to EPA that there is a valid need to hide the chemical identity from competitors and the public.

Of course, one must only consider the Confidential Inventory if the chemical of concern does not appear on the Public Inventory. But even that determination may not be straightforward, because some chemicals are of "unknown or variable composition, complex reaction products or biological (UVCB)." Many of these substances have a CAS number but are further defined for listing purposes by reference to a particular manufacturing process or other qualifier.

If a company not responsible for the initial listing plans to manufacture a UVCB substance on the Public Inventory by a process different than the one included in the definition, that company cannot rely on the Public Inventory listing. It must either file a PMN or determine if the substance manufactured using its process appears on the other portion of the inventory, *i.e.,* the Confidential Inventory.

A Confidential Inventory search is requested by filing a notice of a "bona fide intent to manufacture." EPA, in turn, must respond in 45 days. The agency's response can take one of two forms.

First, if EPA determines that the substance is not on the Confidential Inventory, the agency notifies the submitter of that fact and a PMN then must be filed and reviewed before commercial manufacture can commence.

Second, if the chemical falls into a listing on the Confidential Inventory, the agency notifies the submitter of that fact and of any SNUR restrictions that apply. The submitter then must either comply with the SNUR restrictions or file a Significant New Use Notice (SNUN) with EPA prior to manufacture. A SNUN essentially mimics the PMN notice and review process for the submitter.

Avoiding Traps

As the foregoing summary suggests, the mechanisms involved in checking the Inventory are complex, and traps for the unwary abound. One that can arise is that companies see that a SNUR lists a substance with a generic name that could cover their "new" one, and therefore assume the substance must be on the Inventory and compliance with the SNUR is all that is needed.

In fact, however, if the substance is on the Confidential Inventory, the listing may be more specific than the generic phraseology used in the SNUR, and compliance with the SNUR thus may not be enough. The only way to determine if your particular chemical substance is on the Confidential Inventory is to file a notice of bona fide intent with EPA. Agency staff then will compare the chemical to the complete descriptions of similar substances on the Confidential Inventory.

EPA has addressed similar uncertainties about the Inventory status of nanoscale substances, which have been subject to numerous SNURs in the past several years, and many more are expected. In its 2008 guidance posted on the web, EPA states:

Since EPA generally has not considered units of matter beyond molecules, such as physical aggregates, to be reportable to the TSCA Inventory, EPA has not used particle size to distinguish for Inventory purposes two substances that are known to have the same molecular identity. Under principles of traditional chemistry these different forms of such substances would not be considered different chemicals.[2]

To the contrary, EPA in June issued a fact sheet warning chemical producers that chemicals in a different isotopic form than those listed on the Inventory require a PMN to be submitted. This is not a new agency position, but EPA thought clarification was needed.

EPA also has been considering issuing guidance to change the Inventory status of listed "statutory mixtures" for ceramics, cements and frits, likely to newly require PMNs to be filed for certain of these complex substances.

EPA reached settlements on at least two PMN enforcement cases in 2012, with the larger penalty equaling $1.4 million. The best way for chemical producers and importers to avoid such penalties is to study the TSCA Inventory and PMN process, keep up with new developments and, if any doubt exists, consult experienced experts.

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[1]The statute provides that failure of EPA to act within 90 days allows production to begin. In practice, EPA either reviews the submission within 90 days and concludes it has no concerns, or asks the submitter to agree to an extension. The agency's extensive regulatory powers under TSCA typically encourage the submitter "voluntarily" to agree.

[2]However, EPA also states that the form in which a chemical is manufactured processed, used, or disposed of may play a role in evaluating the risk of a substance and considering whether to address it in some other fashion under TSCA (*e.g.*, SNURs).