

Column

Washington: Initiatives to Watch

By Lynn Bergeson

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On Nov. 25, 2008, the U.S. Environmental Protection Agency (EPA) released for public comment two background discussion documents, one on EPA's Toxic Substances Control Act (TSCA) Inventory Reset initiative and the other on EPA's proposed approach for the Inorganic High Production Volume (IHPV) Challenge Program. Both initiatives are important, and readers are urged to monitor these programs carefully as they evolve, for many reasons.

Inventory Reset Discussion

There are currently almost 84,000 chemicals on the TSCA inventory, with almost 22,000 chemicals added to the inventory through new chemical review since 1979. In 1986, EPA promulgated the Inventory Update Rule (IUR) requiring chemical manufacturers to update production volume data for certain chemicals on the inventory.

At least one problem EPA has identified is that because the IUR does not require reporting for all chemicals on the inventory, it is unclear which chemicals not subject to IUR reporting are in commerce at a given point in time.

EPA is considering a three-year period to "reset" the inventory. The following steps are currently envisioned as part of the clean reset approach:

EPA would place the current TSCA inventory online. This would include specific Chemical Abstracts (CA) index names and Chemical Abstracts Service Registry Numbers (CASRN) for non-confidential chemical substance identities. For chemical substances for which the identities have been claimed as confidential, only generic chemical names and TSCA accession numbers would be provided online.

Persons would certify their chemical substances online by checking or flagging the chemical substances they manufactured or imported during the still-to-be-decided specified timeframe and submitting the certification electronically to EPA, excluding persons manufacturing chemical substances that are not subject to the TSCA Section 5(a) Premanufacture Notification (PMN) reporting requirements and the Microbial Commercial Activity Notification (MCAN) reporting requirements.

At the close of the certification period, EPA would process the certifications and develop a new, interim reset TSCA inventory, containing only those chemical substances that have been certified. A public version of the interim reset TSCA Inventory would be made available online; its availability would be announced in the Federal Register, and persons would have a time-limited opportunity to make corrections to the interim reset TSCA inventory.

Under the clean reset approach, any chemical substances for which a certification was not received would be removed from the TSCA inventory.

Subsequently, if a chemical manufacturer or importer intended to manufacture or import a chemical substance that was removed from the TSCA inventory for non-PMN/MCAN-exempt commercial purposes, a TSCA Section 5 notice (PMN, MCAN or exemption notice) would be required because the chemical substance would be considered "new" under TSCA.

EPA expects to make the reset TSCA inventory available in time for the next IUR reporting period, which is to occur June 1 through Sept. 30, 2011, for chemical manufacturing, processing and use data from the 2010 calendar year.

The TSCA inventory reset initiative has enormous implications for any chemical manufacturer and/or chemical importer, as well as downstream customers and users. If a possible consequence of an initiative is the need to obtain EPA approval for a chemical substance that is now



distributed in commerce as a precondition for continued commercial use, this must be taken very seriously to avoid potential commercial disruption and legal enforcement jeopardy.

A Proposed Way to Challenge

EPA's proposed IHPV Challenge Program follows closely the HPV Challenge Program for organic chemicals that took place from 1998 to 2008. EPA believes the inclusion of an IHPV Challenge Program as part of the Chemical Assessment and Management Program (ChAMP) effort is an important step in characterizing the potential hazard of inorganic chemicals produced or imported into the United States at volumes of greater than 1 million pounds per year. According to the latest figures from the 2006 IUR, there are approximately 750 inorganic chemicals in commerce, 400 to 500 of which are HPV.

EPA defines inorganic chemical substances, according to the TSCA IUR, as chemical substances that do not contain carbon, or contain carbon only in certain forms. Such chemical substances include metals, ammonia, minerals and inorganic acids. EPA's IHPV discussion document provides details on its proposed approach to developing the IHPV Challenge Program.

The Discussion Document

According to EPA, the goal of this effort is to characterize the hazard of HPV inorganic chemicals. "Hazard" includes the physical-chemical properties, environmental fate, environmental toxicity and human health toxicity of chemicals.

EPA notes it intends to utilize ongoing Organization for Economic Cooperation and Development (OECD), Canadian and European Union chemical program initiatives. The OECD program has processed a little more than 100 inorganic chemical HPV cases. Approximately 100 of the 400 to 500 U.S. inorganic HPV chemicals are in the OECD HPV Challenge Program.

EPA also intends to utilize European legislation to regulate chemicals in commerce known as the Registration, Evaluation, Authorization and Restriction of Chemicals (REACH). EPA plans to work closely with both U.S. industry and the European authorities to identify among the list of U.S. HPV inorganic chemicals those that were submitted during the REACH pre-registration process, which ended on Nov. 30, 2008.

EPA is considering the full range of data elements that comprise the Screening Information Data Set (SIDS) and examining their applicability for inorganic chemical hazard evaluation. EPA reportedly is considering changes in the minimal hazard data set to reflect the data elements appropriate for characterization of the range of inorganic chemicals included in this proposal.

The IHPV Challenge Program has critically important implications for the metals and inorganic chemical community and related manufacturers. For chemical producers, there is a real potential for enhanced chemical testing to address perceived data gaps associated with inorganics and/or metals.

Even if readers are not likely to be directly impacted by chemical testing, you could be impacted by the broad circulation of testing results pertinent to inorganics and metals and should be prepared to address these results, as needed.

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