Washington Watch

The Proposed TSCA Inventory Update Reporting Rule: Big Changes Are in Store

Requiring more information on chemical production, use, and exposure

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While debate continues to swirl around whether, and to what extent, the Toxic Substances Control Act (TSCA) needs retooling, just about everyone agrees that the U.S. Environmental Protection Agency (US EPA) needs more information on chemical production, use, and exposure in order to make informed decisions about chemical risk management. Most also agree that TSCA could be put to greater use for these purposes.

The information deficit exists in part because, historically, US EPA has not used its TSCA section 8 authority to require the submission of such information. This is changing, however.

On August 13, 2010, the Agency proposed its much anticipated TSCA Inventory Update Reporting (IUR) Modifications.[1] As discussed below, the proposal telegraphs important changes that are expected to have a significant impact on industry reporting burdens. The modifications will also influence significantly how US EPA goes about collecting the information it needs to make chemical risk-management decisions.

Background: The TSCA Inventory

TSCA section 8 houses the statute's reporting obligations. Under TSCA section 8(b), US EPA is required to keep and maintain a list of chemical substances manufactured or processed in the United States for commercial purposes. This list, referred to as the TSCA Inventory, is widely regarded as a critically important tool that the Agency utilizes to identify, prioritize, and evaluate chemical substances. The Inventory also enables US EPA (as well as other government and private sector interests) to profile domestic chemical industry practices and business patterns in general.

The core Inventory reporting regulations were first issued in 1977, a year after TSCA was enacted.[2] The original Inventory aimed to include all "chemical substances" (as defined by TSCA) that were then being manufactured, imported, or processed for commercial purposes in the United States (except for certain substances that were specifically excluded from the Inventory).

Initial Reporting Under TSCA

The initial reporting under TSCA occurred in phases. During the first phase, chemical-substance manufacturers and importers were required to report information on chemicals manufactured or imported after January 1, 1975, but before June 1, 1979. They had to report on chemical identities, production and import volume, and whether the use of the chemical substance was site-limited (meaning the chemical was consumed entirely on site).

Processors were exempt from the first reporting cycle, and special provisions/exemptions applied to manufacturers defined as "small." During the second reporting phase in the latter part of 1979, processors were authorized (but not required) to report on chemical substances they processed that had not been reported by the

manufacturer or importer in the first reporting phase.

Original IUR

In 1986, US EPA issued its original Inventory Update Reporting rule.[3] The rule required manufacturers and importers of chemical substances listed on the TSCA Inventory to report information pertinent to the production of those chemicals. Reporting information included production volume (by plant site), production plant locations, and certain site-limited activities. The reporting period ran from August 25, 1986, to December 23, 1986.

2003 IUR Amendments

US EPA modified the IUR in 2003, when it issued the Inventory Update Rule Amendments (IURA).[4] The amendments required the submission of more information pertinent to chemical manufacturing sites (including the name of a technical contact for each site, information on the company's corporate parent, and related plant-specific information). It also mandated reporting of more data on exposure.

Requirements for Facilities Manufacturing Large-Volume Chemicals

Importantly, for facilities manufacturing Inventory-listed chemicals in volumes of 300,000 pounds or more, the IURA compelled the production of "readily obtainable" information on the processing and use of such chemicals. Under this requirement, companies "must report information that is readily obtainable by management and supervisory employees responsible for manufacturing . . . ." According to US EPA, "Extensive file searches are not required" to meet this standard,[5] which is intended to be less burdensome than the "known to or reasonably ascertainable by" standard (discussed later in this column).

Producers of chemicals in volumes of 300,000 pounds or greater per site were required to submit specific information, including:

- the type of processing or use operations at the site;
- the North American Industry Classification System (NAICS) codes that best described the site's activities;
- for each NAICS code identified, the industrial function category that described how the chemical substance was used by downstream customers;
- the percentage of the submitter's production volume used in each industrial function category;
- the number of sites where processing or use operations occurred;
- the number of workers reasonably likely to be exposed to the industrial chemical;
- the categories of commercial and consumer uses of the reportable chemical substances;
- an indication of the presence of the reportable chemical in or on consumer products intended for use by children under the age of 14, or a certification that such information was not readily obtainable;

- percentages of the submitter's production volume associated with each commercial and consumer product category; and

- the maximum concentration of the reportable chemical in each commercial and consumer product category.

Controversy Surrounding the 2003 IURA

The 2003 IURA caused quite a stir when it was published. After all, many reporting facilities are not able to generate the required information easily or reliably. For example, it can be very difficult to determine which workers are likely exposed to chemicals and at what concentrations. Similarly, estimates of chemical exposures for consumer products intended for use by children are not an easy calculus.

Not surprisingly, a number of industry organizations challenged the rule. The American Chemistry Council, The Fertilizer Institute, and the Consumer Specialty Products Association, among others, filed suit against US EPA.[6] The litigation was eventually settled. As part of the settlement, the Agency published an extensive IUR question-and-answer document, reporting instructions, and revisions to the final rule.[7]

The Push for More Information: The 2010 Proposed IUR Amendments in Context

It is important to consider the most recent proposed IUR amendments in a temporal context. The foregoing overview of the history of the IUR reporting requirements demonstrates that with each successive revision, US EPA has required the submission of more detailed information, particularly relating to chemical substances produced in large volumes, and with emphasis on chemical exposure and use information.

Since 2003, when the last significant overhaul of the Inventory reporting rule occurred, the demand for more information on chemical exposure and use has accelerated greatly, perhaps in response to criticism that TSCA has failed to elicit such information. Many TSCA detractors view the IUR as an important (but under-utilized) tool for compelling the disclosure of important information relating to chemical production, processing, use, and exposure.

Chemical Management Initiatives at US EPA

At the same time, several US EPA chemical management initiatives — including the US High Production Volume (HPV) Chemical Challenge program and, to a lesser extent, the Chemical Assessment and Management Program (ChAMP) — have highlighted the Agency's need for more detailed information on chemical production, exposure, and use when preparing chemical risk assessments.

Concern at the State Level

Against this federal backdrop, it is important to recognize a growing interest at the state level in limiting or banning certain targeted chemical substances (such as flame retardants and persistent, bioaccumulative, and toxic chemicals). These initiatives have increased exponentially over the past few years as state-level policy makers have grown increasingly dissatisfied with what they perceive to be inadequacies in TSCA regulation.

State concern with TSCA deficits was recently crystallized in the unanimous passage of Resolution Number 10-8 by the Environmental Council of the States (ECOS). This

resolution, adopted on August 30, 2010, called for Congress to enact strong and comprehensive TSCA reform.

Growing Criticism from Environmental Activists

The environmental activist community also has been extremely effective in highlighting significant differences between the U.S. chemical management regime under TSCA and the programs adopted by other countries. In particular, activists have focused on the European Union's Registration, Evaluation, Authorization, and Restriction of Chemicals (REACH) program and certain Canadian initiatives, including the Canadian Environmental Protection Act (CEPA) and Canada's Chemicals Management Plan, and the ability of each to compel reporting of information on chemical production, use, and exposure.

Environmental Defense Fund's celebrated 2007 report *Not That Innocent: A Comparative Analysis of Canadian, European Union and United States Policies on Industrial Chemicals*[8] did much to compare and contrast the chemical management policies of these authorities. The relative lack of chemical information was frequently cited in the report as a major impediment to better risk assessment and risk profiling under U.S. law.

Proposals for TSCA Legislative Reform

All of these forces have coalesced and prompted a Democratic Congress and Administration to seek passage of legislation amending TSCA. As of this writing, TSCA reform measures are pending in both chambers, and a record number of hearings have been held on various aspects of TSCA over the past Congressional session.[9] While legislation is not expected to move forward during the remainder of 2010, it is likely to be considered in earnest in 2011.

Administrative Reform of Chemical Management

Regardless of whatever action Congress may take, the Obama Administration has made it abundantly clear that administrative measures can and will be taken to accelerate the pace of domestic chemical management reform. An unprecedented number of TSCA rulemakings and policy initiatives have been implemented since Administrator Lisa Jackson assumed office in 2009.

These actions include (among other chemical management initiatives) rulemakings that diminish protections under TSCA's confidential business information (CBI) provisions, renewed interest in creating a TSCA section 5(b)(4) "chemicals of concern" list, development of comprehensive chemical action plans for priority chemicals — and, of course, proposed revisions to the IUR.

While each of these initiatives is expected to have a significant impact on domestic industrial chemical production, the proposed IUR revisions are considered by some to have the most far-reaching impacts, as discussed below.

Scope of the 2010 Proposed IUR Revisions

According to US EPA, the most recent proposed rule will affect manufacturers (including importers) of chemical substances and mixtures listed on the TSCA Inventory if they have had production volumes of 25,000 pounds or more at a site in any calendar year since the last IUR principal reporting year. In addition to chemical manufacturers and importers, potentially affected entities may include, among others, chemical users and

processors that manufacture a byproduct chemical substance.

Certain chemicals are exempt from the IUR unless they are subject to another TSCA rule; among the exempted chemicals are naturally occurring substances, microorganisms, polymers, and certain forms of natural gas. In addition, certain chemicals are partially exempt, and manufacturers of such chemicals are required to report only identification and manufacturing information for those chemicals.

According to US EPA, the proposed amendments to the IUR rule would provide improved information that would help the Agency better identify and, where appropriate, "take steps to manage risks associated with chemical substances." US EPA states that it is proposing to modify the rule to meet four primary goals:

- better align the information collected with US EPA's overall information needs;
- increase its ability to provide public access to the information in an effective way;
- obtain new and updated information relating to potential exposures to a subset of chemical substances listed on the TSCA Inventory; and
- improve the usefulness of the information being reported.

The proposed rulemaking includes several sets of proposed changes, as discussed in the following paragraphs.

Reporting Requirements

US EPA has proposed IUR changes that would affect reporting in a number of ways. The proposal would:

- Require the use of electronic reporting software and the Internet to submit all IUR information. Manual submissions would no longer be allowed.
- Require reporting of production volume for all years since the previous principal reporting year (i.e., 2005), rather than just the current principal reporting year. This is a significantly increased reporting obligation, and one that US EPA has signaled previously. Nonetheless, many in industry may not to be prepared to satisfy this requirement if it is implemented.
- Require upfront substantiation of certain data elements when the information is claimed as CBI. The proposal would also impose limitations on the information elements that are eligible for CBI protection.
- Require reporting of process and use information that is "known to or reasonably ascertainable by" the reporting party. This requirement would be more demanding than the current reporting standard, which refers to information that is "readily obtainable." This change, if implemented, is expected to impose particularly significant new reporting burdens on affected industries.
- After the 2011 submission period, require reporting for any substance that meets or exceeds the 25,000-pound threshold in any calendar year since the last principal reporting year.

- Return IUR reporting frequency to every four years (it was increased to five years beginning with the 2003 amendments).

Manufacturing-Related Information

With regard to manufacturing information, US EPA has proposed to require the reporting of certain manufacturing data elements, including:

- whether an imported chemical is physically present at the reporting site;

- the volume of the chemical substance directly exported and not domestically processed or used; and

- when a manufactured chemical (such as a byproduct) is being recycled, remanufactured, reprocessed, reused, or reworked.

Processing and Use-Related Information

With respect to processing and use-related information on chemicals, the proposal would:

- Lower the 300,000-pound threshold for processing and use information to 25,000 pounds. This means that all reporters of non-excluded substances would have to report information in all parts of the IUR Form U.

- Revise the list of industrial-function categories applicable to reporting of processing and use information and replace the five-digit NAICS codes with 48 Industrial Sectors (IS).

- Require reporters to distinguish between consumer and commercial product categories, or indicate if both are relevant.

- Revise and expand the consumer and commercial product category codes used for reporting consumer and commercial use information (using codes developed with Canadian authorities). The proposal would also require an explanation when the "other" product category is selected.

- Require reporting on the number of commercial workers potentially exposed to the reported substance.

Other Proposed Changes

US EPA has also requested comment on several other proposed IUR changes. These changes would:

- Eliminate the 25,000-pound threshold for certain chemical substances that are the subject of particular promulgated TSCA rules and/or orders. This proposal would require manufacturers (including importers) of such chemicals to report under the IUR rule, regardless of production volume. The Agency has requested comment on whether this change should be applied to rules and/or orders that have merely been proposed (but not yet promulgated), and whether a *de minimus* volume threshold should be set.

- Eliminate the IUR reporting exemption eligibility for substances that are subject to an enforceable consent agreement to conduct testing.

- Change definitions to address reporting difficulties related to portable manufacturing, toll manufacturers, and similar situations, and respond to questions and issues that have arisen concerning byproduct reporting. The Agency has developed, and is requesting comments on, draft guidance for such reporting.

Possible Future Actions

US EPA has raised for comment a number of important ideas for future changes to the IUR rule. The approaches on which the Agency seeks comment include:

- further increasing the IUR reporting frequency to every three years, biennially, or annually;

- revising certain reporting exemptions, or eliminating them altogether;

- changing the 25,000-pound reporting threshold to 10,000 pounds;

- changing the IUR reporting requirements to parallel more closely the exposure reporting required on new chemicals via Premanufacture Notification to allow more quantitative assessment of exposure;

- inquiring whether more detailed information on exposure might be collected through the IUR, through a new reporting mechanism under TSCA section 8(a), or through the use of TSCA section 11(c) subpoena authority; and

- expanding the reporting universe to include processors.

While US EPA appears to be only considering these changes, their scope and their identification in the proposed IUR rule offer insight into current Agency thinking. These are important issues, and how US EPA ultimately decides them will have a significant impact on how the Agency goes about obtaining the information it believes it needs to make chemical risk management decisions.

Implications of the Proposed IUR Changes

The proposed changes to the TSCA IUR, when issued in final form, are likely to resolve many of the issues that have confounded US EPA in attempting to use IUR information efficiently, while increasing the information that is available to the Agency for making risk management decisions. At the same time, it is clear that the proposed changes could substantially increase industry's reporting obligations and burden.

Many of the proposed changes come as no great surprise, since US EPA did a good job of announcing its plans beforehand. Actually seeing them in the *Federal Register* is another matter, however, and has caused anxiety in the chemical community. Certainly, changes like lowering the thresholds for reporting and retroactively expanding the time period for reporting production volume from one year to five years fall into the "easier said than done" column.

A major proposed change that caught many people by surprise was the shift from the "readily obtainable" to the more burdensome "known to or reasonably ascertainable by"

standard. The latter covers material in a person's possession or control, including information "that a reasonable person similarly situated might be expected to possess, control, or know." While it is far from clear what this means in practice, all would agree that the new standard would require more effort — perhaps considerably more — to satisfy.

Another concern with the proposal involves the diminished CBI protections available. The proposal to limit CBI claims and require substantiation was not unexpected, given the changes that have already occurred in US EPA's approach to CBI under the Obama Administration.

Next Steps

US EPA intends to issue a final rule in time for the next IUR reporting period, which is scheduled for June 1 through September 30, 2011. In addition, as noted, the Agency has requested comment on a number of areas that could point the way toward significant future changes to the IUR reporting scheme, such as increasing the scope of reporting and expanding the reporting universe to include processors.

These changes, and others down the road, will almost certainly impact not only chemical manufacturers, but also downstream chemical users, including product formulators and, of course, consumer product manufacturers, especially those who make products intended for children.

Interested parties are urged to engage, comment, and be part of a constructive debate about how information should be collected and used for chemical assessment purposes. The success of US EPA's rulemaking effort requires no less.

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Notes

[1] US EPA (2010, August 13). TSCA Inventory Update Reporting modifications, proposed rule, 75 Fed. Reg. 49655-49707.

[2] US EPA (1977, December 23). Inventory reporting regulations, final rule, 42 Fed. Reg. 64572.

[3] US EPA (1986, June 12). Partial updating of TSCA Inventory data base, production and site reports, final rule, 51 Fed. Reg. 21438.

[4] US EPA (2003, January 7). TSCA Inventory Update Rule Amendments, final rule, 68 Fed. Reg. 848.

[5] *See* 40 C.F.R. § 712.7.

[6] *The Fertilizer Institute v. EPA*, No. 03-1077 (D.C. Cir. 2002). On September 6, 2006, the Agency issued minor amendments to the IUR. See US EPA (2006, September 6). TSCA Inventory Update Reporting Rule, electronic reporting, 71 Fed. Reg. 52494. The modifications were largely technical in nature, and not substantive.

[7] US EPA (2005, January 26). TSCA Inventory Update Reporting Revisions, 70 Fed. Reg. 3658.

[8] The report is available online at http://www.edf.org/documents/6149_NotThatInnocent_Fullreport.pdf.

[9] In the US House of Representatives, Congressmen Bobby L. Rush and Henry A. Waxman have introduced the Toxic Chemicals Safety Act of 2010 (H.R. 5820). In the Senate, Senator Frank R. Lautenberg has introduced the Safe Chemicals Act of 2010 (S. 3209). For more on this topic, see Bergeson, L. L. (2010, Autumn). Washington watch: TSCA reform: Legislative action begins. Environmental Quality Management, 20(1), 85-99.