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TSCA Reform: The Push For More Disclosure

Law360, New York (November 15, 2010) -- Almost every day, newspaper and magazine articles throughout the country reference the potential environmental, health and safety hazards of chemicals in the U.S. The Toxic Substances Control Act, 15 U.S.C. § 2601 et seq., and its implementing regulations are the primary mechanism through which the U.S. Environmental Protection Agency regulates the manufacture, distribution and use of chemical substances in the U.S.

The TSCA charges the EPA with ensuring that the use of chemical substances in this country does not pose an adverse risk to human health or the environment. In large part, the EPA accomplishes this task through the assessment of information provided by entities that manufacture, import, process and distribute chemical substances before and after those chemicals have been placed into the stream of commerce.

Recently, however, concerns have been raised as to whether the TSCA provides the federal government with sufficient power to regulate chemical substances, especially in light of recent regulatory developments in Europe, which have been more focused on ensuring chemical safety before chemicals enter the marketplace. In addition, recent efforts by the EPA to broaden the scope of information that is made available to the public have also been a concern for chemical manufacturers.

This article 1) provides a brief overview of existing TSCA chemical reporting requirements; 2) examines the current efforts to reform the TSCA both via congressional action and EPA and state efforts; and 3) provides practical tips to companies on how to best comply with TSCA reporting requirements while still shielding themselves from unforeseen liabilities associated with misinterpretation of information.

TSCA's Information Gathering Mechanisms

In order for the EPA to assess the potential risks associated with the manufacture and use of a particular chemical substance, the agency must have access to information concerning the potential health and environmental effects of the substance. As a result, information gathering is a central component of the TSCA, both before and after chemical substances are placed in commerce.

However, a common critique of the current state of TSCA regulation is that the TSCA merely requires submission of information in the possession of the chemical manufacturer; it does not require a manufacturer to generate new environmental health and safety (EHS) data.

Before a chemical substance can even be introduced into commerce, chemical manufacturers must provide "pre-manufacture" notification to the EPA. 15 U.S.C. § 2604(a)(1)(A).

These notifications are required 90 days prior to manufacture or processing and must be accompanied by information related to chemical identity, production volume, byproducts, uses, disposal practices and potential for environmental release and human exposure. 40 CFR § 720.45.

The regulations specifically require that an entity submitting a pre-manufacture notification must include "all [existing] test data in the submitter's possession or control which are related to the effects on health or the environment." 40 CFR § 720.50.

Although incomplete studies are not required to be provided to the EPA, a submitter must include a description of those studies, including any "significant preliminary results." Instruction Manual For Reporting Under The TSCA §5 New Chemicals Program, www.epa.gov/opptintr/newchems/pubs/tscaman2.pdf.

The EPA requires similar notification if a chemical substance is going to be used in "a significant new use." 15 U.S.C. § 2604(a)(1)(B).

Through evaluation of the information submitted with the pre-manufacture and significant new use notifications, the EPA makes a determination as to whether to restrict the new chemical substance or its use in any way.

For chemicals that are already in commerce, the TSCA provides mechanisms for the EPA to gather data on an ongoing basis. See 15 U.S.C. §§ 2603; 2607. Again, however, except in limited circumstances, the EPA generally lacks the authority to require the generation of EHS data. Under TSCA Section 4, the EPA must make significant findings related to risk of injury to health or the environment and a lack of data before it can force the regulated community to generate EHS data on existing chemicals. See 15 U.S.C. § 2603(a).

As a result, the EPA relies heavily on existing data when evaluating the potential EHS impacts of chemical substances already on the market. Section 8 of the TSCA is the primary means through which the EPA collects such data, chiefly pursuant to Section 8(e). Section 8(e) requires the prompt reporting to the EPA of "information which reasonably supports the conclusion that [a chemical] substance or mixture presents a substantial risk of injury to health or the environment." 15 U.S.C. § 2607(e).

EPA guidance defines "substantial risk of injury to health or the environment" as "a risk of considerable concern because of (a) the seriousness of the effect and (b) the fact or probability of its occurrence." TSCA Section 8(e); TSCA Section 8(e); Notification of Substantial Risk; Policy Clarification and Reporting Guidance, 68 Fed. Reg. 33129, 33138 (June 3, 2003).

This reporting requirement is fairly broad in terms of who must report and the types of information that must be reported. Section 8(e) reporting also must be done in a relatively short time frame. EPA guidance requires that entities subject to this provision submit the relevant information within 30 days of receipt. 68 Fed. Reg. at 33138.

This timing, coupled with the fact that the EPA requires that EHS information contained in limited studies, preliminary results and draft reports be reported (see, e.g., 68 Fed. Reg. at 33139), has the potential to result in incomplete information being submitted to the EPA. Nonetheless, once those reports are provided to the EPA, they become part of the public record and are then readily available for public consumption. See e.g., the EPA's website at www.epa.gov/oppt/tsca8e/pubs/8eandfyisubmissions.html for access to 8(e) submissions since September 2001.

The TSCA does allow for reporting entities to claim that certain information is confidential. See, e.g., 15 U.S.C. 2613; 40 CFR §§ 716.55; 717.19; 720, Subpart E; 721.11. However, especially in the case of information related to health and safety studies, the allowability of such confidentiality claims is quite limited (and becoming increasingly more so, as discussed in the next section). Id.

TSCA Reform

Legislative Reform Attempts

Beginning in 2009 and continuing through 2010, Congress began to focus its attention on reforming the TSCA. On April 15, 2010, Senator Frank Lautenberg, D-N.J., introduced the Safe Chemicals Act in the Senate, and on July 22, 2010, Democratic

Reps. Henry Waxman and Bobby Rush, of California and Illinois, respectively, introduced the Toxic Chemicals Safety Act in the House.

Each of these bills was generally intended to require the generation and disclosure of potential adverse impacts of chemicals on human health and the environment.

For example, the Toxic Chemicals Safety Act would require that chemical manufacturers and processors submit to the EPA a "minimum data set" for all new chemical substances, including information such as characteristics; volume manufactured, processed or reported; exposure; and uses to support a demonstration that each substance meets a stringent "reasonable certainty that no harm will result" safety standard. (See, HR 5820 Section 6.)

Other provisions would require that chemical manufacturers and processors submit declarations for all chemical substances or mixtures manufactured or processed, describing such information as health and safety studies and details about where manufacturing, processing or distribution occurs. (See, HR 5820 Section 8.)

The bills also seek to modify the process for protecting confidential business information, making it more structured and limited. However, as a result of the recent midterm elections, it is doubtful TSCA reform will be a priority in what remains of 2010 (and the expected legislative gridlock will likely prove to be a substantial obstacle to reform in 2011).

The EPA's Information Access Efforts

The EPA also has been very busy since 2009 and has taken a number of steps to reform its chemical management program within the TSCA regulatory framework. These steps include implementing "Action Plans" for a number of specific chemicals, such as perfluorocarbons, bisphenol A, lead and mercury; proposing to amend the TSCA Inventory Update Rule in order to increase reporting requirements; and increasing public access to chemical information.

Increasing public access to chemical information (or conversely restricting industries' ability to claim confidentiality with respect to such information) has been a significant focus of recent EPA efforts. For example, the EPA announced in March 2010 that it would provide free access to the TSCA Chemical Substances Inventory, which contains the vast body of information maintained by the agency on industrial chemicals manufactured and processed in the U.S.

In May 2010, the agency added a substantial amount of information about chemicals and TSCA-regulated facilities to its Envirofacts database, which is a publicly available resource that provides a central access point for a number of EPA databases containing information about environmental activities.

The EPA has also specifically targeted confidentiality claims. In January 2010, the EPA announced its new general practice with respect to confidential business information claims, indicating that it intends to deny these claims if the chemical identity claimed to be confidential 1) "[i]s already publicly available on the TSCA Chemical Substances Inventory," and 2) "is submitted under TSCA § 8(e) as part of — or data from — a health and safety study." 75 Fed. Reg. 3462 (Jan. 21, 2010). In May 2010, the EPA reiterated and clarified its January 2010 "general practice." 75 Fed. Reg. 29754 (May 27, 2010).

State Actions

States are also taking action to compel the disclosure of EHS-related information. For example, Maine requires that manufacturers or distributors of children's products containing a chemical identified by the state as a "priority chemical" notify the state if any of those products are sold in Maine.

Washington has passed a bill that similarly imposes reporting obligations on manufacturers of children's products that use identified chemicals of concern, and other states, such as Oregon and Vermont, are currently considering bills with analogous requirements. Several states also have or are considering bills which authorize the state's participation in a multistate clearinghouse on toxic chemicals.

Similarly, as part of its Green Chemistry Initiative, the State of California has begun the rulemaking process for a regulation on consumer products that would, among other things, require producers, importers and even trademark owners to provide information to DTSC, perform an alternatives assessment on any products identified by DTSC as "priority products" that contain "priority chemicals," and comply with DTSC requirements imposed after review of the alternatives assessment.

All of these actions have at their core a desire to expand the scope of information that must be disclosed and to provide greater public access to the information. The next section provides some procedural tips for chemical manufacturers in light of these new initiatives.

Practical Tips

The TSCA expressly states "that the Administrator shall consider the environmental, economic, and social impact of any action the Administrator takes or proposes to take under this chapter." 15 U.S.C. § 2601(c).

While the EPA may be required to consider the economic impact of its implementation of the TSCA, one of the unintended (and likely not considered) economic effects of both the existing regulatory scheme and the proposed reforms may be the unforeseen liabilities associated with misinterpretation of publicly available information that the EPA requires to be submitted.

Because this unintended consequence is not accounted for and the existing protections (such as confidentiality) are crumbling, entities need to be aware and take into consideration the possible misuse of any submitted information. The following are ways to minimize potential liability from the mischaracterization of this type of publicly available information.

- Ensure that the information that is being reported is accurate and consistent. There may be instances in which a company is required to report information to the EPA as well as a state regulatory authority and it is important that the information submitted to the various authorities match.

- Consider whether any of the reported information can properly be characterized as trade secret and/or confidential business information in light of the EPA's recently announced policy to generally deny confidentiality claims.

- When submitting data include any explanatory information that might be applicable in order to ensure that anyone viewing this information is educated as to the scope of the information and purpose for which the data has been generated. The source of the data should be clearly understood. For example, under Section 8(e), regulated entities must submit to the EPA any information which reasonably supports the conclusion that a substance presents a substantial risk of injury to human health or the environment. The information submitted does not constitute an admission by the reporting entity that the information is accurate.

- Where information is required to be submitted within a short time frame such as with Section 8(e), consider supplementing with more refined information as it becomes available.

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