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New TSCA Requirements Present Substantial Challenge to Manufacturers That Produce or Import Chemical Substances

Beginning in 2005, manufacturers and importers of any of the roughly 76,000 chemical substances listed on the Chemical Substances Inventory maintained by EPA under the Toxic Substances Control Act ("TSCA Inventory") will be subject to new and expanded reporting and recordkeeping requirements. These new requirements are imposed by amendments to the TSCA Inventory Update Rule ("IURA") promulgated by EPA in January 2003, and are codified at 40 C.F.R. Part 710.

The new rules are not solely applicable to those who manufacture saleable chemical substances as final products, or who import identifiable chemical substances into the country. Rather, the reporting requirements are potentially applicable to all companies that create a chemical substance listed in the TSCA Inventory as the result of a chemical reaction during any step in a manufacturing process – even if that listed chemical substance is part of a mixture or later transformed into a different chemical substance. The new reporting requirements are also potentially applicable to those who import chemical substances as part of a larger mixture – for instance those who might import certain types of solvents, fuels, or other items that contain any of the listed chemical substances. As a result, the new rules are of significance to all U.S. companies engaged in manufacturing or extraction industries – not just to chemical manufacturers.

Although not great in length, the new rules are not easily applied. They contain numerous exceptions for specific industries, specific types of activities, and specific listed chemical substances. Some of these exceptions are described below. Many key terms in the regulations (for instance, the definition of "manufacture" itself) are not well defined, so that companies will have to use their best judgment to determine whether reporting of certain chemical substances is or is not required.

The burden to assimilate and implement the new TSCA requirements may be considerable. For the first time, manufacturers and importers of inorganic chemical substances will have to compile production volume and worker exposure information. In addition, those who manufacture large volumes of organics will have to collect production and use information regarding downstream uses of those substances.

Background

TSCA authorizes EPA to gather information from those who manufacture and import chemical substances to determine whether chemical substances in commerce pose unacceptable risks to human health and the environment. To fulfill its information-

gathering role, EPA in 1977 promulgated the original Inventory Update Rule, which focused on obtaining volumetric information with respect to non-polymeric organic chemicals manufactured at any single site in volumes exceeding 10,000 pounds per year. Under the new IURA rules, which become effective in 2005, EPA will be collecting information about a much broader range of chemical substances, and will be requiring more extensive reporting about those substances.

Pursuant to the new rules, any person that manufactures or imports a listed chemical substance in quantities of 25,000 pounds or more at any site during 2005 must report various data (Tier 1) to EPA during 2006 respecting that substance and the number of workers exposed to that substance. Moreover, those who manufacture or import more than 300,000 pounds of a listed chemical substance at a given site during 2005 are subject to a second tier (Tier 2) of reporting in 2006 relating to the downstream processing and use of listed substances by others. After 2005/2006, the reporting requirements will be triggered every four years (so that the next reporting cycle will be the 2009/2010 calendar years). Unlike the previous (and more limited) reporting requirements in effect prior to 2005, the new reporting requirements apply to inorganic, as well as organic, chemical substances listed on the TSCA Inventory.

EPA has stated that it intends to use the information gathered under the new rules for a wide variety of purposes, including: to screen chemicals in commerce for risk; to identify chemicals to which large numbers of workers and consumers are exposed; and to initiate and support other EPA health, safety, and environmental protection initiatives.

In approaching the new rules, a company should ask the basic questions listed below.

Do I Handle a "Chemical Substance" That is Subject to the IURA?

Only "chemical substances" listed on the TSCA Inventory are subject to reporting under the new rules. To constitute a chemical substance for purposes of the IURA, a substance need not exist in "pure" form or have been isolated from a material of which it forms a part. Rather, a listed chemical substance will be potentially subject to reporting even if it is part of a mixture containing other chemical substances. As such, chemical substances contained in production process streams, final saleable products, and materials imported from outside the customs territory of the U.S. are potentially subject to the reporting requirements.

The TSCA Inventory lists approximately 76,000 chemical substances. The non-confidential portions of the TSCA Inventory can be purchased in written or electronic form from the National Technical Information Service (see http://www.ntis.gov). In addition, although it has not been peer reviewed by EPA, a searchable online database maintained by Cornell University has incorporated the TSCA Inventory (see http://msds.pdc.cornell.edu). Also, persons can contact the Chemical Abstract Service (http://www.cas.org), or EPA directly to determine whether a particular chemical substance in listed on the TSCA Inventory.

TSCA and the new IURA rules exempt certain categories of listed substances from the reporting requirements. These include: (a) most polymers; (b) microorganisms;

(c) "naturally occurring chemical substances" that are unprocessed or have been minimally processed by certain specified methods; (d) certain forms of natural gas; (e) pesticides; (f) tobacco products; (g) source, special nuclear, and byproduct material; (h) pistols, firearms, shells, and cartridges; and (i) food, food additives, drugs or cosmetics. Many of the above exemptions contain conditions and exceptions, and a company must carefully review them before relying on the exemption.

Other types of chemical substances have "partial exemptions" under the rules, such that they are subject only to the Tier 1, but not the Tier 2, reporting requirements. These include: (a) a large number of petroleum process streams and other chemical substances listed in the rules; and (b) inorganic chemical substances. The partial exemption for inorganic chemical substances, however, only applies to reporting for the 2005/2006 reporting cycle. During subsequent reporting cycles (*i.e.*, beginning in 2009/2010), the Tier 2 reporting exemption for inorganic chemical substances will no longer be applicable.

Do I Manufacture or Import a Listed Chemical Substance for a Commercial Purpose?

The new TSCA reporting rules apply only to persons who "manufacture" chemicals listed on the TSCA Inventory "for a commercial purpose." The term "manufacture" includes not only the production of a listed chemical substance, but also the importation of a listed chemical substance into the customs territory of the U.S.

A chemical substance will be deemed imported if it is part of any mixture containing the chemical substance. Thus, if a chemical substance is imported as part of a larger mixture such as a solvent, antifreeze, fuel or some other substance that is used in the production process, then that chemical substance is potentially subject to the reporting requirements. Note, however, that a person will be deemed an importer for purposes of the reporting requirements only if that person is responsible for first bringing the chemical substance into the customs territory of the U.S. A manufacturer that purchases a chemical substance (or mixture containing a chemical substance) from a U.S. supplier will not be deemed to have imported the chemical substance, even if the U.S. supplier itself initially imported the chemical substance from overseas.

Manufacture is defined unhelpfully as including the "manufacture" or "production" (as well as importation) of a chemical substance. Manufacture is distinguished from the term "processing," which means the preparation of a chemical substance after its manufacture for distribution in commerce. EPA has stated that mixing existing chemical substances together, without the occurrence of a chemical reaction that changes the form or nature of any of the constituent chemical substances, constitutes "processing" rather than manufacturing (and therefore does not trigger reporting). Conversely, EPA would likely consider any creation of a listed chemical substance during a production step in manufacturing through a chemical reaction that occurs during that production step, to be "manufacture" for purposes of the TSCA reporting requirements.

To be potentially reportable, a chemical substance must not only be manufactured (or imported), it must be manufactured (or imported) for a "commercial purpose." This

includes producing or importing the chemical substance (or material in which the chemical substance is incorporated) for commercial distribution (*e.g.*, as a saleable product or for test marketing), or for use as an intermediate or other input in any step of a production process.

Conversely, chemical substances that are "impurities" or that are part of waste streams are not considered produced "for commercial purposes," and are therefore not subject to the reporting requirements. EPA defines "impurity" as a chemical substance which is unintentionally present with another chemical substance or mixture. Additionally, "byproducts" that will be further processed to recover useful products are generally not reportable. A byproduct is a chemical substance produced without a separate commercial intent during the manufacture, processing, use, or disposal of another chemical substance or mixture.

Do Any Other Exemptions from the Reporting Requirements Apply?

The rules provide several additional exemptions from IURA reporting requirements. No reporting is required for chemical substances that:

- are part of "non-isolated intermediates," which the rules define as production streams that are not removed from a "continuous" flow process;
- are manufactured or imported solely in small quantities (*i.e.*, no greater than reasonably necessary) for research and development purposes;
- are imported as an article or part of an article;
- result from a chemical reaction that occurs due to exposure of another chemical substance or a material containing a chemical substance to environmental factors, such as air, moisture, microbial organisms or sunlight;
- result from a chemical reaction that occurs incidental to the storage or disposal of another chemical substance or mixture;
- result from a chemical reaction that occurs upon the end use of another chemical substance (such as the use of adhesive, paint, fuel, or solvents); and
- are formed when a chemical agent is added to another chemical substance to impart a particular physiochemical characteristic.

Moreover, small manufacturers are exempt from the reporting requirements.

Do I Manufacture (Including Import) Sufficient Quantities of Non-Exempt Listed Chemical Substances at an Individual Site?

For each non-exempt listed chemical substance that one manufactures or imports, IURA reporting requirements only apply if the volume exceeds 25,000 pounds or more of the

substance at a single site during 2005 (or subsequent reporting years). Those who manufacture and import the same chemical substance at a single site must aggregate the respective volumes to determine whether the 25,000 pound threshold is exceeded. EPA considers the import site to be the site of the organization that is directly responsible for importing the substance (which can be the corporate headquarters). Those who manufacture or import mixtures must determine for each reportable chemical substance in the mixture whether the reporting threshold is exceeded. Those who manufacture or import hydrates should adjust the production volume to exclude water because the IURA requires reporting of the anhydrous form of the substance.

What Information do I need to Report?

Manufacturers (including importers) who determine that they are subject to IURA reporting (*i.e.*, submitters) must comply with the reporting requirements that correspond to their production volume. All manufacturers that produce or import nonexempt chemical substances in quantities greater than 25,000 pounds in 2005 (or any subsequent reporting year) at any site must submit Tier 1 information for each such chemical substance. This information includes:

- a certification statement signed and dated by an authorized official;
- the specific chemical name and CAS number for each reportable chemical substance;
- whether the chemical substance is manufactured or imported, or both, at the site;
- whether the chemical substance is site-limited (i.e., only processed and used at the site, not distributed to others);
- the total volume (in pounds) of the chemical substance manufactured at the site (the amount must only be reported to two significant figures of accuracy provided that the reported figure is within ten percent of the actual volume);
- the total number of workers reasonably likely to be exposed to the chemical substance at the site;
- the physical forms of the chemical substance and associated percentages in each form (rounded off to the nearest ten percent) as it leaves the site; and
- the maximum concentration (measured by weight percent and specified as a range) of the chemical substance at the time it is sent off site.

Submitters are required to report this information to the extent that the information is known or reasonably ascertainable by them. This standard requires submitters to collect and report information that is in their possession or control as well as information that a reasonable person similarly situated might be expected to possess, control, or know. Accordingly, submitters must conduct extensive file searches, if necessary, to obtain the information.

Non-exempt submitters who produce more than 300,000 pounds of a reportable chemical substance during 2005 (or a subsequent reporting year) must also submit Tier 2 information. Tier 2 requires information to be submitted regarding use and processing operations conducted at sites that receive the reportable chemical substance from the manufacturer, even if indirectly through a broker or customer of the manufacturer.

Tier 2 reportable information includes:

- type of industrial processing or use operation at each downstream site that receives the chemical substance;
- North American Industrial Classification System (NAICS) codes that describe the industrial processing and use operations at downstream sites;
- for each NAICS code, the industrial function category (from a list prepared by EPA) that best represents how downstream customers use the chemical substance;
- for each combination of processing/use designations, NAICS codes and industrial function categories:
    - the estimated percentage, rounded off to the nearest ten percent, of the total production volume associated with each combination,
    - the estimated number of downstream sites (specified as a range) at which the chemical substance is processed or used, and
    - the estimated number of workers reasonably likely to be exposed to each chemical substance at all sites at which the chemical is used or processed.
- identification of the commercial and consumer product categories that best describe the products in which the chemical substance is used, including an indication of whether the products are intended for use by children under the age of 14; and
- estimated typical maximum concentration of the reportable chemical substance in each commercial and consumer product category.

For Tier 2, submitters must compile and report information that is readily obtainable, which imposes a lesser burden on the submitter than the known or reasonably ascertainable standard applicable to Tier 1 reporting. To meet the readily obtainable standard, submitters are not required to conduct extensive file searches or to survey downstream customers. Rather, the submitter only needs to collect information that is known by the submitter's management and supervisory employees responsible for manufacturing, processing, distribution, technical services and marketing of the reportable chemical substance.

How Do I Report?

Submitters must prepare a separate form for each chemical substance at each site that exceeds the reporting threshold. Submitters must report the information on Form U, which is currently being revised by EPA. Submitters may report on paper or electronically.

Must I Keep Records?

Submitters must retain records that document any information submitted to EPA for a period of five years from the last day of the submission period (*i.e.*, records for reports submitted in 2006 must be kept until December 23, 2011).

Can I Assert That My Information is Confidential?

Submitters may claim certain information is Confidential Business Information (CBI) if there is reason to believe that the information would reveal trade secrets or confidential commercial or financial information. EPA has specific procedures for CBI claims regarding manufacturing plant site information, chemical identity, and chemical production volume, including production ranges. CBI claims must be asserted to EPA at the time IURA information is submitted. Submitters must provide upfront substantiation for CBI claims for plant site identity and chemical identity.

Practical Recommendations

The new TSCA rules impose significant data gathering and reporting obligations for manufacturers and importers of chemical substances, and particularly for those who manufacture or import inorganic substances (because such persons were not subject to the IURA in the past). Manufacturers should promptly devise a strategy for determining whether they are subject to the new reporting rules and for compiling the required reportable information.

Manufacturers should consider the following actions:

- promptly review the TSCA Inventory to gain a sense of the types of chemical substances that are listed;

- identify all materials (other than articles) that the company imports into the customs territory of the U.S., and determine whether any reportable "chemical substances" are part of such materials;

- based on existing information (including interviews with knowledgeable employees), create flow diagrams of each production process, and other operation, conducted at every site operated by your company. The flow diagram should show all of the inputs into the production step, and all of the outputs (including final products, intermediate products, byproducts and waste streams). The flow diagram

should also indicate all of the chemical reactions that occur during each production step, or other operation;

- identify any chemical substances created through a chemical reaction. Any such created chemical substances, other than impurities or other than those contained in byproducts and wastes, are potentially reportable, unless one of the exemptions from the TSCA rules (such as the non-isolated intermediate exemption) applies;

- review the TSCA rules to determine the applicability of any other exemptions to reporting a particular chemical substance that is manufactured or imported; and

- determine whether the company satisfies the threshold volumes for reporting Tier 1 or Tier 2 information.

If, after this inquiry, the company believes that it must report either Tier 1 or Tier 2 information, then it should begin to gather that information, so that it will be able to report it as required in calendar year 2006. Additionally, the company should determine if CBI claims are warranted to protect trade secrets.

For further information about the TSCA Inventory Update Rule Amendments, please contact:

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