Understanding TSCA

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The Toxic Substances Control Act (TSCA) was enacted in 1976 by Congress and placed under the management of the Environmental Protection Agency (EPA). The act provides a broad authority for the assessment and control of new and existing chemicals as they may pose potential threats to the occupational workforce, the public and the environment. Materials in commercial use prior to 1976 were "grandfathered" and were added to the initial TSCA inventory without review or approval. New chemical substances placed into commerce since that time have required registration with the EPA prior to manufacture or importation. There are currently over 83,000 compounds on the inventory.

New Chemical Substances & Exemptions

A new chemical substance is one in which there exists no listing on the TSCA inventory. Once it has been established that the material is a new chemical substance, the material must be notified, if no exemption applies. The EPA has granted exemptions, if the material or its use is outside of its jurisdiction (e.g. materials solely used in drugs, cosmetics or food products) or if the EPA has deemed that no review or that an abbreviated review is more appropriate. The TSCA exemptions consist of

- Low Volume Exemption (LVE)
- Research and Development (R&D)
- Test Marketing Exemption
- Low Release / Low Exposure (LoREX)
- Polymer Exemption

The most often used exemptions are the LVE, R&D and polymer exemptions. The R&D exemption applies only to substances manufactured or imported solely for developmental purposes. Substances under this exemption may not be placed into commerce. The LVE limits manufacture and importation of the substances to 10,000-kg/yr. Lastly, the polymer exemption permits certain polymer substances to be placed into commerce with very limited reporting provided the polymer meets certain requirements.

It is also important to keep in mind that certain substances may also be exempt from reporting under TSCA. These may include naturally occurring substances, hydrates (where the parent molecule is registered), substances manufactured for export only, un-isolated process intermediates and certain salts.

Registration Process

The principle means of notification is via the Premanufacture Notice (PMN) process. The PMN allows for unlimited production or importation, provided the review does not flag any EPA concerns. This is the only method, which adds the new chemical substance to the TSCA inventory; however, the listing may be masked as confidential.

Information required for the PMN notice includes substance, impurity and by-product identification, use information, expected volumes manufactured or imported, potential sources of occupational and environmental exposures and toxicological and physical property data, if applicable. Toxicological / ecotoxicological and physical property data are not required, but if the new chemical substance falls into certain categories of compounds, it is strongly recommended or the EPA may likely impose limitations on the volume, limitations on release or use of the material.

The review period for the PMN is 90 days and a submission fee of $2500 is required (there is a provision of a lesser amount for small companies). The review can result in no action, an issuance of a consent order or a Significant New Use Rule (SNUR). The major difference with the latter two actions is that a consent order is promulgated only for the PMN submitter, whereas a Significant New Use Rule applies to all manufacturers, importers and potentially processors of the substance. A consent order or SNUR may require additional testing, particular personal protection, hazard communication, use or release restrictions or recordkeeping. A substance, which has a SNUR imposed upon it, requires all new manufacturers or importers of the substance to notify the EPA

through the PMN process of their intent at least 90 days prior to placing the material into commerce.

It is important to note that the LVE notice is the same as the PMN; however, the EPA review is shorter (30 days) and requires no fee. While the process of notification under the LVE is quicker, it is critical to keep in mind that a chemical exempted in this way is manufacturer, process and site specific. Only under certain circumstances can changes be made without re-notification. This is something that should be thoroughly considered before simply filing an LVE to get a particular material into commerce quickly.

Actions Required After the PMN Review

The new chemical substance is not automatically added to the TSCA inventory. This is not accomplished until a Notice of Commencement of Manufacture or Import (NOC) is filed with the EPA. The NOC is required within 30 days of the first batch either manufactured or imported after the PMN review period is complete. The batch must be intended for commercial use.

Substances of Concern

The EPA has grouped a number of compounds into a set of "categories of concern". These categories have been developed over time based on the EPA's experience with certain compounds belonging to these groups, which may share similar toxicity profiles and pose similar risks either to workers or the environment. If a new chemical substance fits into the description given for one or more of these categories, it does not necessarily mean that the substance will share the concerns imposed upon the group, but it does mean that the manufacturer should be prepared to provide data showing that the compound does not share the concerns of the larger grouping.

Some of the compounds, which have been flagged for concerns, are anilines, epoxides, glycol ethers, nickel compounds, vinyl ethers and materials which fit the description for persistence, bioaccumulative and toxic (PBT). This latter category has attracted much attention and the EPA has likewise regulated many materials belonging to this group. Any compound, which exhibits PBT characteristics is likely to be denied registration. One primary example of a PBT is a perfluorooctane sulfonate compound (PFOS). The EPA provides guidance for all of these categories, which may include main hazards and suggested testing strategies.

Another recent category of concern, which needs special mention involves the classification of nanomaterials as new chemical substances even though the substance, itself, may have been previously listed. The reasoning behind this is that because of the size of the nanomaterial it may be significantly more bioavailable and may cause harm to the public or if released into the environment.

Just because a chemical lacks categorization does not indicate that there may not be an issue. The EPA may utilize analogous compounds and group contribution type calculations in determining whether a material is hazardous occupationally or to the environment. This may particularly be the case in the absence of data.

Other Provisions of TSCA

All of the discussion so far has centered on Section 5 of TSCA. There are other provisions, which allow the EPA to regulate or take action on materials, which they believe could pose a undue hazard to the workforce, public or the environment. This includes the following sections:

- Section 4 – allows the EPA to require testing on substances, which the EPA would like to understand better or which they believe could pose a significant threat.
- Section 6 – allows the EPA to regulate or ban certain chemicals, which are known to be hazardous to health or the environment.
- Section 8 – requires that manufacturers maintain records and report certain adverse effects associated with chemicals.
- Section 12 – requires exporters of certain chemical substances to notify the EPA / other nations.

Section 8 is particularly important to understand, since there are time critical documentation or reporting requirements associated with it. Section

8(c) requires recordkeeping of allegations or adverse reactions, whether substantiated or not. Records are maintained internally. Section 8(e) requires the reporting to the EPA of evidence of substantial adverse effects or injury, where the effect has not been previously known or reported for a particular substance. The EPA must be notified of certain details within 15 days.

One tool that the EPA uses to assess and prioritize the risk of larger scale commercial chemicals is the Inventory Update Rule (IUR). Companies, which manufacture chemicals in amounts greater than or equal to 25,000 pounds (300,000 pounds for processing and use), are required to report certain data to the EPA. This includes site, manufacturing, volume, use and exposure information. Reporting under the IUR is required every 5 years. This was last done in 2006-7 for the 2005 calendar year. It will be required again in 2011 for the 2010 calendar year.

What's on the Horizon for TSCA?

In light of recent changes in chemical control legislation in the European Union and elsewhere...and the fact that there have been no significant changes to TSCA since 1976...there has been a push to re-vamp the law. As industry and the EPA would rather implement a program, which more responsibly tackles the issues of safe chemical use and regulation, several actions are likely to be taken over the next couple of years.

Based on data from the IUR the Chemical Assessment and Management Program (ChAMP) was developed to broaden the EPA's effort to ensure the safety of existing chemicals. The ChAMP program expands on the High-Production Volume (HPV) Challenge Program. Under the ChAMP program there are an estimated 6,750 substances, which are under re-assessment. Based upon these assessments, substances will be prioritized and appropriate actions may be taken by the EPA. This may include issuing Section 4 test rules and regulating some of these materials.

Two others initiatives under ChAMP will be to include the re-assessment of large-scale inorganic substances and to reset the TSCA inventory to more accurately reflect chemicals currently in commerce. The proposal to reset the inventory was discussed in 2008 and it is likely to resemble the process, which created the original TSCA inventory. This may involve companies nominating chemicals currently in commercial use over a 3 year period. Those chemicals not in use will be removed from the inventory and those substances will require re-notification, if commercial need is subsequently required. Further detail is expected to be announced in 2009 or 2010.

Conclusion

While TSCA may seem like an overwhelming set of regulations, it is quite systematic in its approach to assessing and regulating the risk of hazardous materials as they may negatively impact workers, the public and the environment. With a little thought and planning TSCA should not pose a significant impediment to the timely introduction or continued use of materials, even with some of the proposed changes, which may be implemented in the future. This underlies the need for a periodic risk assessment program, so that extremely hazardous materials can be phased out and substituted for a more sustainable product.

About ChemOne Compliance, LLC

ChemOne Compliance, LLC was established in 2005 to serve the needs of the chemical and chemical-related industries, which may require assistance in the management of chemical compliance. The company is located in the heart of New England, specifically in the Mt. Monadnock Region in southwestern New Hampshire, but serves a client-base throughout the US and internationally. The company has expertise in risk and safety assessements, material safety data sheet (MSDS) authoring, new chemical regulations and safety / compliance training. Additional information can be found at www.chemonecompliance.com.

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