

COMPLEX REGULATORY LANDSCAPE CREATES COMPLIANCE CHALLENGES

By Jytte Syska, 3E Company Europe

The last two years have given shape to a complex regulatory landscape, with the United Nations' Globally Harmonized System of Classification and Labeling of Chemicals (GHS), the European Union's (EU) Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) regulatory framework, and the United States' anticipated reform of the Toxic Substance Control Act (TSCA), taking center stage. GHS and REACH in particular have become essential components of corporate account globalization plans, with their impact being felt throughout the entire chemical lifecycle and global supply chain.

In September 2009, U.S. Assistant Secretary of Labor Jordan Barab announced a proposed rule to align the Occupational Safety and Health Administration's (OSHA) Hazard Communication ("HazComm") Standard with provisions of the U.N. Globally Harmonized System of Classification and Labeling of Chemicals (GHS). This announcement heralds significant changes to the HazComm Standard in 2010 and 2011, with proposed revisions including both philosophical and tactical changes to hazard communications.

If accepted, these revisions will have far-reaching implications for Material Safety Data Sheet (MSDS) and label authoring, publishing, distribution, and management. The proposal also includes revised criteria for the classification of hazardous chemicals, as well as changes to definitions and terms used in the standards, and new training requirements for employees. When the final rule is promulgated, companies will face many challenges, including re-evaluating how their substances and mixtures are classified, re-issuing MSDSs and labels, and training staff as appropriate.

The final rule will be promulgated sometime around March 2011. Companies will be prohibited from implementing this regulation until the final rule is

promulgated. They will have three years to come into compliance with the final rule and two years to implement associated training requirements. In addition, there are 26 states and territories with their own OSHA-approved plans, and these states and territories will have six months to adopt comparable provisions of the final standard. In the meantime, individual state plans will remain in effect until they adopt the required revisions.

GHS is challenging to implement, especially in countries such as the U.S., Japan, and Korea, where multiple regulatory authorities govern different aspects of the hazard communication requirements. In the United States, OSHA, the U.S. Environmental Protection Agency (EPA) acting under the authority of the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Consumer Products Safety Commission (CPSC), and the Department of Transportation (DOT) are working to implement GHS. Each agency has the right to adopt GHS in a way that best suits its purpose, with no consideration given to a unified approach or timeline.

Achieving compliance with the new HazComm Standard will be challenging for many companies, especially since U.S. GHS requirements are still evolving. The risk of errors or misinterpretations can persist, which demands access to regulatory expertise.

One of the most significant shifts will be for companies accustomed to complying with OSHA's regulation in the United States. Those companies will need to shift from a risk-based classification approach to a hazard-based classification approach. Instead of considering the likelihood or probability of an event occurring, classification will be absolute under GHS. The introduction of symbols and pictograms, similar to what has been used for transport of hazardous goods for many years as part of the labeling is also a relatively new concept in the United States.

Many Asian countries—including Ja-

pan, Taiwan, China, Korea, New Zealand, Indonesia, and Russia—as well as European nations have implemented GHS, but not always in its entirety, which results in differences in how the classification results are presented on both the MSDS and on the labels. In Europe, companies will be required to follow a harmonized (mandatory) classification of certain substances for certain endpoints. Korea and Japan also have official lists of recommended GHS classifications for substances.

As much as GHS is meant to drive global harmonization, individual countries are allowed to select the physical hazards, the health and environment classes, and the associated categories within each class that they wish to adopt, and most countries that have implemented GHS have chosen to keep some of their existing hazard classification and communication that is not yet part of the GHS. As a result, there will be far less harmonization between countries and regulatory authorities within each country than originally anticipated.

"REACHING" FOR SUCCESS

The REACH regulation went into effect on June 1, 2007, at the same time simplifying and complicating the compliance work for companies manufacturing products in Europe or importing into or exporting from Europe. As a result of the legislation, all companies manufacturing, importing, distributing, or using chemical substances (on their own, in mixtures or in articles) in Europe, are required to closely examine their chemical inventory for substances within the scope of the regulation to ensure compliance. The European Chemicals Agency (ECHA) has been established to efficiently manage the system.

Key components of the REACH mandate are the following:

- Registration of manufactured/imported chemical substances;
- Increased information and communication throughout the supply chain;
- Evaluation of some registered substances;
- Authorization for use of substances of very high concern; and

- Restriction of the use of certain substances for specific applications.

Non-EU companies should establish and maintain a good and reliable inventory of substances in all chemicals that are exported to the EU. Each substance must be identified by Chemical Abstracts Service (CAS) number, European Inventory of Existing Commercial Chemical Substances (EINECS) number, etc. and the amounts exported to the EU must be known. All test data that is owned by the company must be identified as it will most likely need to be shared with other companies in the Substance Information Exchange Forum (SIEF).

If the non-EU company uses mixtures for producing the products that are exported to EU, the chemical composition of these mixtures must be known, as well as the producer of the substances.

Potential registrants should consider whether the company can handle the registration and the other requirements under REACH by itself, as this requires that the company have an EU subsidiary that can do the work. Possible alternatives are to have the company's EU customers register the substance or substances, or appoint an "Only Representative" (a person or company legally established in Europe who takes over the responsibilities for the substance under REACH). Outsourcing is also an option. In any case, the non-EU company has to play an active role during the registration of the substances. Depending on which solution the company chooses, request for information related to the pre-registration that has been done and the registration should be expected from the EU customers.

Momentum is also building for significant TSCA reform in the United States. On December 30, 2009, EPA Administrator Lisa Jackson announced a new initiative with a comprehensive approach to enhance the agency's current chemicals management program within the limits of existing authorities. This effort includes requirements for the following: new regulatory risk management actions; development of Chemical Action Plans, which will target the agency's risk management

efforts on chemicals of concern; providing information needed to understand chemical risks; and increasing public access to information about chemicals.

Many companies will be affected by these changes, as almost every business involved in the chemical industry is impacted by TSCA in some way (with some exceptions among food, drug, cosmetic, nuclear, and pesticides companies). In addition, raw materials, intermediates and finished goods are regulated by TSCA. Full life-cycle, or cradle to grave, compliance is an essential component of TSCA, and most manufacturing/importing, processing and disposal activities are TSCA regulated.

If companies do not comply with TSCA, they could face severe legal repercussions, including criminal and civil penalties, damage to a company's brand or reputation, and negative impact on a company's ability to do business. Personnel that demonstrate willful and knowing non-compliance also face imprisonment.

The risk of financial damage is also high if a company is non-compliant, as non-compliant companies may receive fines and penalties and experience a loss of business revenue if production is stopped.

To ensure compliance with TSCA, experts recommend developing and maintaining a comprehensive and detailed plan, which should include the following:

- TSCA inventory: Checking the TSCA inventory for substances imported or manufactured, including the ingredients in finished products;
- TSCA R&D exemption: Reviewing R&D exemption requirements and setting up procedures to govern related activities;
- Import certification: Obtaining import certification once the status of the substance or product to be imported has been checked against the TSCA inventory;
- Export notification: Establishing processes for tracking 12(b) exports and assisting with export notification;
- Adverse effects: Establishing processes for compliance with adverse effects reporting and recordkeeping;

- Regulatory tracking: Monitoring and tracking regulatory changes which are likely to impact business; and

- Record-keeping: Maintaining required records and auditing against various recordkeeping requirements.

Achieving environmental regulatory compliance can be a daunting task, especially with the regulatory landscape constantly shifting and changing. Strong processes, applications, and systems are needed to support the various aspects of compliance management for GHS, REACH and TSCA. The following tasks can also help facilitate compliance at your company:

- For REACH Registration compliance, conduct a detailed portfolio analysis and establish an inventory with REACH role—M/I (Manufacturer/Importer) or DU (Downstream User), tonnage, classification (current and EU/GHS), and registration requirements;
- Obtain raw material MSDSs and of full composition of mixtures;
- Identify possible registration, authorization, and restriction requirements;
- Update or re-author documents and labels according to GHS and REACH;
- Develop a full understanding of the REACH registration process; and
- Training to help with identifying responsibilities and establishing an action plan for REACH, GHS, and TSCA.

Companies that are impacted by GHS, REACH or TSCA can also seek assistance from information management service providers, such as 3E Company, that are well-versed in data and other content and information as it relates to global EH&S regulations and who thoroughly understand the global regulatory environment. These providers can also assist in implementing compliance activities into the organization, and can help facilitate compliance with these increasingly complex and changing global chemical regulatory obligations.

Jytte Syska is president of Ariel Operations and managing director of 3E Company Europe. 3E Company is a global provider of chemical, regulatory, and compliance information services. Syska can be reached 45-70-22-81-70 or jsyska@3ecompany.com.