

A helping hand

REACH As application of the REACH legislation rolls on, 3E Company's *Jytte Syska** reminds industry of its obligations and explains how outsourcing REACH compliance can be a commercially attractive option, particularly for affected companies outside the EU

The EU's Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) Regulation went into effect on June 1, 2007, simplifying but also complicating the compliance work for companies manufacturing, importing or exporting into Europe. As a result of the new 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.

Key components of REACH mandate the following:

- registration of manufactured/imported chemical substances
- increased information and communication throughout the supply chain
- evaluation of some registered substances
- authorisation for use of substances of very high concern
- restriction of the use of certain substances for specific applications.

The European Chemicals Agency (ECHA) has been established to efficiently manage the system.

Understanding the scope

The scope of REACH is vast and there are several issues that could impact a company's ability to meet their obligations under REACH. Companies based outside the EU may not be terribly familiar with the Regulation. For example, a paint manufacturer in the US, whose products are used in cars exported to Europe, may find itself unexpectedly subjected to REACH. Such manufacturers may not have the knowledge necessary to readily support their European importers to comply with the REACH Regulation. As such, importers will need to know the background of each substance used in their product, including European hazard classification and other information included in the Safety Data Sheet (SDS). Given the wide scope of the regulation, REACH is expected to have a huge impact on the supply chain.

Chemical manufacturers located in North America may also have a hard time dealing with the new regulation. While US regulatory bodies have in the past allowed manufacturers to claim "proprietary information" when completing forms, this is unacceptable under REACH.

Manufacturers will now need to provide detailed information regarding the composition of all chemicals. The basic principle is that no substance within the scope of REACH can be imported into Europe unless it has been registered. The registration requirement is per importer per substance.

The European importer of substances will have to participate in the Substance Information Exchange Forum (SIEF) for each substance and work with the other members of that SIEF to prepare the registration dossiers. This requires data sharing and certain part of this data would have to be supplied by the manufacturer of the substance.

The content of SDSs has also changed and expanded under REACH. Additional information is required and the information must be aligned with the information in the registration of the substance. When an exposure scenario has been required as part of the REACH registration of a substance, every SDS for a product containing this substance must have the exposure scenario attached.

Authorisation of the use of certain substances is a new concept introduced in Europe by REACH. The list of substances that are subject to authorization (Annex XIV) was issued in June 2009 and will be updated regularly. Continued use of substances included in Annex XIV requires that after the 'sunset date' the use has been authorised.

Dealing with REACH

Non-EU companies should establish and maintain a good and reliable inventory of substances in all chemicals (substances, mixtures and chemicals in articles) that are exported to the EU. Each substance must be identified by CAS number, 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 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(s) of the substances contained in them. Eventually, the non-EU user who exports a product to the EU and the producers of the constituent substances will need to have agreement regarding which company will have responsibility for eventual

late pre-registration and for the registration under REACH.

A company in scope of the requirements needs to consider if it can handle the registration and the other requirements under REACH itself as this requires that the company has an EU subsidiary that can do the work. Possible alternatives are to have the company's EU customers register the substance(s), or appoint an 'Only Representative' (a person or company legally established in Europe that 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 substance(s). Depending on which solution the company chooses, requests for information related to the pre-registration that has been done and the registration should be expected from EU-based customers.

A number of useful guidance documents and other information can be downloaded from the ECHA web site (<http://echa.europa.eu>).

The outsourcing option

Complying with REACH can be a daunting task, and working with an outsourced solution provider can help ease the burden. Companies that choose to work with an outsourced solution provider should look to choose one that offers the following solutions:

- training that can help with identifying responsibilities and establishing an action plan
- help with the portfolio analysis by establishing an inventory with role (M/I or DU), tonnage, classification (current and EU/GHS) and registration requirements
- obtaining raw material MSDSs and full composition of mixtures
- assistance with substance identification
- identification of possible registration, authorisation and restriction requirements
- SDS preparation, including the update of documents according to REACH, and
- assistance during the registration process.

Choosing the right outsourced solution provider can help free up internal company resources, saving valuable time and money.

**Jytte Syska is president of Ariel Operations and managing director of 3E Company Europe. She has more than 20 years of experience as an EH&S regulatory expert.*