



DIRECTOR'S CORNER



“REACH will have far-reaching impacts.” Forgive the play on words but that is exactly what is going to happen. I had the opportunity to attend a 1-day workshop on a new European Community legislation referred to as Registration, Evaluation, and Authorization of Chemicals (REACH). Even though REACH is a European Union legislation, because of some of the elements of the upcoming legislation, impacts are expected to be felt worldwide.

The evolution of REACH started with the publication of a White Paper in 1998 aimed at protection of human health and environment and maintenance and enhancement of the competitiveness of the European chemical industry. After making it through a myriad of European Union rulemaking processes, REACH is now being deliberated by the European Parliament and the European Council of Ministers. Conventional wisdom is that sometime at the end of 2006 or at the latest in early 2007, REACH will receive final approval as a European Union regulation. Already, efforts are underway to establish a brand new European Agency headquartered in Helsinki to manage and implement REACH.

REACH will establish a single coherent system for new and existing chemicals that will establish requirements for pre-registration, registration, evaluation, and authorization of chemicals. About 30,000 chemicals are initially expected to be covered by REACH requirements. The pre-registration process is expected to take about 12-18 months and would require the submission of information such as substance name, potential significant details (*e.g.*, third party representative), deadline for registration, and similar substances. The Helsinki REACH agency would then publish a list and related information on web site. The idea is to provide companies with the opportunity to come together to share data.

The registration process would include the development of a chemical safety assessment that would include hazard and exposure information, development of exposure scenarios, development of safety data sheets, and risk management procedures. The registration process consists of development and submittal of physical/chemical, environmental, and health effects that include the following:

- Physical/chemical property dossier
- Chemical safety report including life cycle analyses as appropriate
- Collect and share existing data on properties of substances and generate new information including animal testing, if necessary
- Prepare safety data sheet (SDS) and provide SDS to downstream users and distributors
- Classify and label using globally harmonized system
- Develop and communicate risk management measures

The Evaluation process is expected to ensure that industry is meeting obligations and unnecessary testing is prevented. The Authorization process is to ensure that risks from substances of high concern are properly controlled. In some cases, the Agency might limit or discontinue the usage of certain chemicals based on evaluation and authorization analyses.

The foregoing discussion provides a brief summary of the myriad and extensive requirements of REACH. However, the impact of this forthcoming European legislation will be felt much farther and wider than the European Union. For example, consider a product that is manufactured somewhere outside the European Union and then imported into the European Union. If the product (in case it is a pure substance) or

any of the constituents (if the product is a mixture) is a REACH-listed chemical, then the importer is obligated to comply with the requirements of REACH. Thus, there could possibly be extensive implications both up and down the supply chain. Some of the scenarios that could lead to the unavailability of certain chemicals are:

- Based on analyses conducted during the evaluation and authorization steps, the agency might limit or discontinue the usage of a chemical
- Based on costs involved for REACH compliance, a supplier may decide to stop production of a certain chemical
- Because of the limited demand for a certain chemical, the supplier may stop production of the chemical regardless of the costs involved for REACH compliance

REACH will have extensive impacts on the chemical industry in the European Union. However, as discussed above, because of supply chain implications combined with the stringent requirements of REACH, the impact of REACH is likely to be felt worldwide.

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