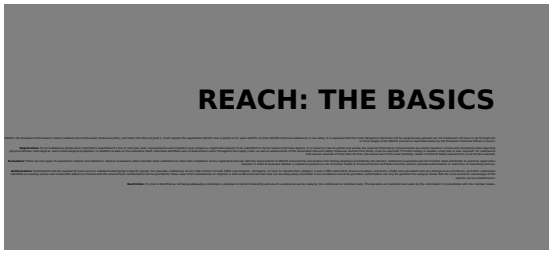
Reaching Too Far?

Experts debate what the domino effect will be of the European Union's newly initiated and controversial chemicals policy

By Joy LePree



Despite attempts by the global chemical industry to fight the European Commission's REACH proposal, the legislation passed at the end of 2006. Now, the industry is bracing for its impact. REACH stands for the registration, evaluation, and authorization of chemicals. The legislation &#151 with its requirements for submitting registration dossiers, chemical evaluations, and authorization documents for substances sold, manufactured, or imported to member states of the European Union &#151 demands that chemical industry participants dealing in the European Union register all existing and future substances with a newly established European Chemicals Agency. Under the law, about 30,000 existing substances will have to be registered within the first 11 years. These substances are prioritized based on produced or imported annual volume.

"REACH is currently the most ambitious chemical legislation in the world and a marked improvement over the current situation," says EU Environment Commissioner Stavros Dimas. "More information will be available about substances in everyday products, and it is expected that the most dangerous substances will be progressively substituted with safer alternatives. REACH will also encourage innovation in the chemicals industry and increase consumer confidence in their products."

While Dimas' outlook is undeniably favorable, some experts suspect that the impact on the global chemical industry is not as bright. "REACH will have an impact well beyond manufacturing and importing of chemicals into Europe," says Mike Walls, managing director of technical and regulatory affairs with the American Chemistry Council (ACC). "It has an impact globally for every manufacturing industry that uses chemicals or makes articles or consumer products that contain chemicals. "For the chemical industry, there will be a lot of supply chain issues in terms of ensuring that appropriate information has been collected and reflected in the registration dossiers. There will be potential proprietary interests at stake around data sharing and compensation. There are also issues with respect to the generation and collection of test data and participation in consortia. There are a host of issues with respect to authorization of chemicals including how to create a substitution plan,

getting a use-specific license and determining what substances are considered available alternatives."

What Does It Mean?

REACH, according to most experts, will have the greatest impact on the supply chain. "Because chemical manufacturers will need to report what substances are in their mixtures and products, this is going to force information sharing up and down the supply chain," says Yve Torrie, project manager with the Lowell Center for Sustainable Production, University of Massachusetts Lowell. "A lot of manufacturers are going to find it difficult to get that sort of information from their suppliers. If suppliers are not willing to share that information, they will most likely be dropped by their manufacturers who need to register substances within a mixture.

"On the other side," she continues, "there might only be a tiny bit of substance needed, and the supplier of that substance will decide it's not worth it to do data requirements, so they will drop that chemical from their offerings. If that happens, it will leave some manufacturers unable to produce their products, so they will need to find another supplier or look at reformulating without that substance."

Specialty chemical manufacturers may face similar difficulties, says James Cooper, senior manager of chemicals policy with SOCMA. "Batch manufacturers that make five or six batches a year of a specialty chemical may choose not to manufacture certain products because the margins aren't high enough for them to operate in a particular chemical market when faced with the costs of registering each component of the batch," Cooper explains. "Specialty chemical manufacturers make these kinds of decisions all the time, but REACH may really force their hand to stop production of some substances."

And in general, some firms that manufacture or import substances into the EU may decide that the cost of compliance is not worth the effort. "The relatively small size of the market just doesn't make the high cost of registration and application worthwhile for some market players, and they will inevitably pull out," says Walls. He believes these REACH ramifications, when combined, are likely to cause short- and long-term disruption in the market.

Some cultural changes are also anticipated. For example, consortiums among companies with similar market interests will most likely be formed in an effort to share research and data. "The hard part will be figuring out how to do this in an equitable fashion when the people at the table are true competitors," says Cooper. He believes small players will be especially challenged. "The confidentiality of information for small businesses is one of the key factors of concern regarding REACH. Often the only competitive advantage a small firm can gain over their competitors is by keeping their trade secrets and business relationships confidential, especially when it comes to certain performance chemicals or specialty chemicals. Small businesses may get crushed by the loss of information."

And, despite the predictions of the EU's Dimas, some believe REACH will negatively

impact innovation. "REACH will certainly become a barrier to innovation because it imposes significant costs, which will most likely be paid out of the R&D budget, so there is likely to be some impact on technology and innovation," says Walls. SOCMA's Cooper agrees. "If you look at the EU's chemical directives prior to REACH, they did have upfront test costs and a no-data, no-market type of approach, and if you then look at the number of new molecules that have been introduced into the EU's commerce over the last 10 years compared to what has been introduced into the U.S., which uses a risk-based approach, there are orders of magnitude of difference," says Cooper. "In the U.S., there may be 1,300 to 1,500 new chemicals introduced per year, compared to that number over a decade in Europe."

However, Torrie says her organization doesn't see much impact on innovation. "The industry line is that testing and data collection is taking money from R&D, but the fact is that industry should already be doing environmental safety and health work and should have the data for existing chemicals. In addition, REACH data requirements for substances between one and 10 tons are minimal. So, REACH is not as difficult for industry in the sense of small quantities. So R&D, in small quantities, shouldn't be hindered," she says. Also, "if a mixture requires authorization, and a substitute is needed, or if a supplier drops certain products, it will encourage industry to innovate and find a substitute that doesn't need authorization or tons of environmental data because it should be a safer alternative," she adds. "And in the long run, safer chemicals are financially better for chemical manufacturers because they aren't dealing with compliance and disposal costs."

What Should Be Done?

Despite the gloomy outlook, REACH is law, and industry participants who want to continue doing business in Europe must get on board. The good news is there is time to prepare, since the various deadlines for registrations, evaluations, and authorization take place over a period of years with the first pre-registrations due by Dec. 1, 2008. Experts suggest industry participants use this time wisely.

"While REACH only applies to manufacturers and importers in Europe, in a global economy manufacturers and suppliers around the world will be expected to comply," says Walls. "This period of the calm before the storm provides an opportunity for them to get basic information together." ACC suggests developing an inventory of substances or mixtures produced, exported, or purchased from the EU. "That should include the entire value stream &#151 suppliers as well as customers," explains Walls. "During this process, manufacturers may be able to identify potential consortia partners with whom they can share the burden of the associated paperwork." He also thinks it's worthwhile for companies to collect and evaluate existing hazard data. "That will help a company decide how it might seek a

waiver for data requirements under REACH. It will also be an opportunity to identify what data and studies people already own, which will be helpful under the data compensation and sharing arrangement that will need to be developed under REACH."

While these preparation steps sound easy enough, the question remains: Do most chemical processors have the resources to cope with REACH? The answer is a mystery.

"Whether a company can handle REACH depends on a lot of factors," says Torrie. "A lot of the larger companies have toxicologists and people involved in environmental health and safety research, so they may already have much of the needed data. But small- and medium-sized companies will have less of that." She adds: "My sense is that everyone, even large companies, will need some sort of REACH-specific training to learn the basics of reporting. And certainly small- and mid-sized companies will need consultants and will probably need to bring someone in house if they want to continue doing business in the EU." She believes the companies that will find it the hardest to get by in the REACH environment are "those that need authorization or to find substitute chemicals, those that don't already have working environmental safety and health departments, laggards within the industry that have refused change, and those who prepare specialty chemicals." She says these groups will have to change their culture in order to keep doing business in Europe.

Whether REACH will drive business out of the EU or drive companies out of business remains to be seen over the next few years, but industry experts suspect that it will take time to determine how it all plays out. "While the intent of REACH is not to drive people out of business, finding the right balance is going to be challenging initially. Since this is a new venture, the magnitude of this kind of regulation is an experiment. No region in the world has gone to this degree before, so it's really a wait-and-see approach as far as the total impact it will have on the chemical industry and on the European economy," says Cooper.

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