REACH

Changing the nature of regulatory framework

In 2007, when REACH came to effect, it replaced about 40 different regulatory programmes with a single set of rules for the management of chemicals in the European Union (EU). This will change the nature of chemical regulatory by requesting the industry to demonstrate the safety of chemical manufacturing and usage. Compliance requires manufacturers and importers to go through a registration process with deadlines determined by volume and hazards.

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REACH is the EU's programme for Registration, Evaluation, and Authorization of Chemicals. It establishes a staggered time period for manufacturers and importers to provide full safety dossiers on their chemicals. 'The users must know what they are using or handling' is the motivation behind this scheme. The deadline for each substance depends on how much of it is made and its hazard category. November 30, 2010 was the deadline for dossiers to be submitted for all substances manufactured or sold in quantities of 1,000 metric tonne per year or more. If a substance is not registered, it will be illegal to manufacture or sell it within the EU.

However, if a manufacturer or importer wants to take advantage of the staggered registration, which can go up to 2018, the chemicals should have been pre-registered. Otherwise, they could not be sold in the EU after the beginning of 2009 without immediate complete registration. 'No data, no market' is the motto of REACH.

REACH aims to improve protection of human health and environment by placing responsibility on the industry to ensure that chemical substances are managed and utilised safely. It is intended to enhance worker safety by making more information available about chemical hazards and risk management measures. It also requires consideration of the health and environmental impact of chemicals throughout their life cycle. Chemicals and products that do not meet these requirements cannot be sold in the EU, unless specifically exempt. The regulations agreed in 2007 are meant to introduce safeguards governing the safety of thousands of chemicals utilised in various sectors.

Regulations impose new requirements

By introducing one set of regulations applicable throughout the EU, the programme supersedes a hodgepodge of regulations that had

accumulated in the different member countries over the past few decades. It establishes several categories of rankings, based on volumes produced & consumed and perceived hazard levels. It also applies to both individual chemicals, or substances, and finished products, or articles that contain chemicals. All definitions have been set by the European Commission and the European Parliament, and these bodies established European Chemicals Agency (ECHA) based in Helsinki, Finland, to administer REACH.

REACH imposes 'registration' requirements on each EU manufacturer or importer of chemical substances, whether on their own, in preparations, or in articles containing such substances where these are intended for release during normal and reasonably foreseeable conditions of use, in quantities of 1 metric tonne (1,000 kg) or greater per year, unless such substances are exempted. Polymers meeting the definition under REACH are generally regarded as presenting limited safety risks and are exempt from registration under REACH.

Monomers present at above 2 per cent weight by weight in the finished polymer and other substances, however, must be registered if the total quantity of any such monomer or other substance is greater than or equal to 1 metric tonne per year. The fact that monomers are designed to be consumed in the reaction process is not relevant from a REACH perspective. This provision to register monomers and other substances meeting these conditions applies to importers of polymers into the EU as well as to polymer manufacturers in the EU unless such substances have been registered by an actor up the same supply chain.

Being responsible

Thousands of companies had signed up through the ECHA online registration programme, pre-registering more than a million chemicals. The chemicals being pre-registered were introduced in the European marketplace prior to 1981; chemicals introduced after that time underwent more rigorous pre-market testing and did not need to go through the new certification process.

REACH timeline

Registration will continue through 2018, as follows:

- **June 1, 2007:** REACH becomes operational; ECHA established in Helsinki
- **June 1-December 1, 2008:** Preregistration takes place
- **January 1, 2009:** Chemicals not preregistered cannot be sold or imported in EU
- **December 2010:** Registration required for chemicals produced at 1,000 metric tonne or more per year, for chemicals of very high aquatic toxicity in volumes of 100 metric tonne or more per year, and for extremely hazardous chemicals in volumes of 1 metric tonne or more per year
- **June 2013:** Registration required for chemicals in volumes of 100-1,000 metric tonne per year
- **June 2018:** Registration required for chemicals in volumes of 1-100 metric tonne per year

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A pre-registration file for a substance consists of three basic pieces of information:

- The substance identity. ECHA stated in June 2008 that 98 per cent of the first batch of pre-registrations it had received relied on standard identifiers such as CAS or International Union of Pure and Applied Chemistry (IUPAC) names
- The envisaged deadline and production quantity for the registration
- The name and contact information of a company or third-party representative who will act as the contact point for data sharing. This can be a manufacturer, an importer, or a customer using the chemical

The substance identity is particularly important because it will help the agency assign potential registrants to the same Substance Information Exchange Forum (SIEF). SIEF was formed for each pre-registered substance as a means for companies to share data and other information. The goal was to reduce duplication of tests, particularly animal tests. Producers could also form voluntary consortia to divvy up tasks in collecting and analysing test data.

Chemicals produced in limited quantities, primarily for R&D, may be exempt from the pre-registration requirement, although a notification requesting an exemption for this status had to be submitted to the agency.

One of the earlier companies to pre-register their substances in June 2008 was the BYK Division of German specialty chemical producer Altana. The company asserted that it completed REACH pre-registration in only four days.

Because REACH will cover all chemicals imported into the EU – either as identifiable entities or incorporated into finished products – its impact will be felt around the world. Foreign manufacturers could be represented in the registration processes only by an appointed representative located in the EU. That person is responsible for fulfilling REACH obligations, including memberships in SIEFs and consortia.

Industry groupings had formed consortia, even before ECHA assigned SIEFs. For example, in March 2008, tin producers and consumers announced the formation of an inorganic tin compound group that aimed to minimise REACH-related costs and resource requirements. The group had encouraged potential new participants, including all manufacturers, EU importers, and users of inorganic tin chemicals to join.

And on a more basic level, a Lower Olefins and Aromatics (LOA) consortium was formed. The LOA consortium was open to any company, European or otherwise, manufacturing or importing these compounds. Downstream users and other data holders were also invited to play an active role in the consortium.

Leaders in registration

As is typical for big firms, Dow is the so-called lead registrant for most of the products that it has submitted for registration. The lead registrant is the company that files the data package for a particular chemical; the other companies that produce or import it then follow, linking their submission on manufacturing process and customer end-uses to the primary filing.

In most cases, major companies have much of the data, so it made sense that they lead the registration process. Dow is the lead registrant for 60 chemicals that exceed the 1,000-metric-tonne volume threshold, and more than 100 employees have been involved in the data compilation and reporting effort.

The lead registrant has a critical role, consolidating all data on the chemical, including physical properties, toxicology data, and exposure testing results. In addition, the lead company is charged with facilitating information exchange between registering companies, using the SIEF online discussion to ensure that all available data are considered. Although ECHA provides the software support for the forum, discussions are run entirely by the companies, and it is their responsibility to organise and plan their data collection to prepare the chemical registration.

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Concerned downstream users

One important target audience of the European Chemical Industry Council (CEFIC) and ECHA support documents is downstream chemical users. This group is less familiar with the regulation and has been concerned about what it could mean for the supply of key raw materials. Some end-users have been panicking. Some suppliers have been providing them with weekly updates on what chemicals have been registered, but that had not eased their concerns. It should be also noted that most requests for deadline extensions, none of which have been granted, have come from worried end-user.

Problems have arisen because of the high costs of testing and certification, which can amount to hundreds of thousands of Euro for each chemical. The costs may mean some key substances – used in small quantities in products such as adhesives, plastics or paints – may fail to receive the necessary registration even though replacing them is difficult for users in 'downstream' industries.

A big worry for many companies is that certain products they need contain small amount of chemicals that are difficult to identify, often because they are part of secret formulations withheld by suppliers on competitive grounds. For example, specialised coatings for the aerospace industry utilise about 200 different materials. Since each material contains an average of 5-10 chemicals, companies rely on at least 1,000 individual substances. ■

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