REACH: The New European Union Chemicals Regulations

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Regulation (EC) No 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals, adopted on 18 December 2006, (REACH) is intended to overcome the limitations of the previous European Union (EU) chemicals regime and to establish a comprehensive regulatory framework for the management, control, and use of chemicals. REACH aims to provide a high level of protection of human health and the environment through earlier and improved identification of the inherent properties of chemical substances.

REACH marks a centralised approach to European regulation, with a strong role for the supranational institutions. It replaces a network of directives by one regulation. Unlike directives which must be transposed into domestic law by the EU Member States, EU regulations are directly and uniformly applicable in all Member States without national implementation. REACH also establishes the European Chemicals Agency (ECHA) to administer the new chemicals regime and provide scientific expertise to the Commission. It redefines the relation between Member States and the EU in the context of risk regulation. The Commission-led decision-making process is intended to speed up the process.

The principle underpinning REACH is "no data, no market." All chemicals must be registered. Any unregistered chemical must be taken out of circulation after the transition dates (between 30 November 2008 and 31 May 2018 depending on tonnages). Another underlying principle of the new chemicals regime is that manufacturers, importers, distributors, and downstream users must ensure that substances that they manufacture, use, or place on the EU market do not adversely affect human health or the environment and are adequately controlled. REACH shifts the responsibility for understanding and managing the risk associated with the use of chemicals to industry, rather than the EU Member States.

REACH requires manufacturers or importers of chemicals above one tonne per year to gather data regarding the health and environmental properties and risks of their substances and to demonstrate that they are safe to use.

REACH imposes a comprehensive registration requirement. It targets about 30,000 substances which are currently on the market but for which there is little or no information. It ap-

plies not only to substances on their own but also in preparations and articles containing chemical substances intended to be released during normal and foreseeable conditions of use. Registration is based on the submission of a technical data file. It extends previous data reporting requirements, which affected new substances placed on the EU market, to chemicals manufactured in the EU for export only. This requirement rebuts allegations that REACH is a protectionist regime intended mainly to close the EU market to third-parties' imports. This article focuses on the main aspects of REACH.

Pre-registration. The beginning of the pre-registration process on 1 June 2008 marked the first milestone of the new chemicals regime. Existing substances ("phase-in substances" in the REACH Regulation) benefit from phased registration deadlines provided their manufacturers or importers pre-register them before 1 December 2008. This process allows companies to continue manufacturing and importing pre-registered substances for several years until the registration deadline expires. In order to pre-register a substance, a company must create an account with the ECHA's portal and submit basic information, consisting of the company's name and contact details, the name of the substance, the anticipated registration deadline, and the tonnage. Pre-registration should enable companies intending to register the same substance to set up substance information exchange forums (SIEF), where companies may share data, on a voluntary basis, and are required to share the results of animal testing studies in order to limit them.

Manufacturers, importers, distributors, and downstream users must ensure that substances on their own, in preparation or in articles are pre-registered during the pre-registration window to be able to manufacture or import them into the EU after the pre-registration window closes on 30 November 2008. Missing the pre-registration window means that manufacturers and importers of existing substances cannot benefit from a delayed deadline for full registration of phased-in substances, and, instead, such substances must be regarded as new substances subject to full registration before being manufactured, used, or placed on the market. Although it was anticipated that 180,000 pre-registration files would be submitted, more than 350,000 pre-registration dossiers had been submitted by mid-September 2008.

Registration. Registration for pre-registered phase-in substances will apply gradually to facilitate transition to REACH. The next milestone after the pre-registration phase is the first registration deadline for high-volume and very dangerous substances in 2010. The registration dossier must contain a technical dossier, for substances whose volume is 1 tonne or more per year and a chemical safety dossier for substances whose volume is 10 tonnes or more per year. The technical dossier contains information on the properties, classification, and uses of a substance. The information required varies depending on the substance's tonnage; the requirements are set out in Annexes VI and XI of the REACH Regulation. An exposure assessment and risk characterisation are also required for substances classified as dangerous, persistent, bio-accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB).

Non-EU manufacturers exporting to the EU cannot pre-register or register their substances themselves. They must either let their EU importer pre-register or register their substances or appoint an EU-based "only-representative." By appointing an only-representative, companies get more control over the registration process and avoid having to disclose confidential or sensitive information to the importer. Guidance on appointment of only-representatives addresses several issues which, it had previously been argued, discriminated against non-EU manufacturers compared with their EU competitors. Only-representatives who act on behalf of more than one non-EU manufacturer for the same substance must submit a separate registration for each manufacturer of that substance. This clarification removes concerns that only-representatives would need to submit a single registration aggregating the tonnages of the same substance, which could have resulted in non-EU manufacturers having to comply with heavier data submission requirements and earlier registration deadlines than those imposed on their EU competitors manufacturing equivalent tonnages.

Confirmation that the registration provisions are not straightforward came in March 2007, when an application to the High Court for judicial review was made against the Department for Environment, Food and Rural Affairs, the government department responsible for implementing REACH in the United Kingdom. The application sought confirmation that the REACH requirement to register monomers was inconsistent with the exemption of polymers from registration, as monomers are chemically indistinct from the polymers. On 11 October 2007, in *R (on the application of SPCMA SA & Others) v. Secretary of State for the Environment, Food and Rural Affairs [2007] EWHC 2610 (Admin)*, the High Court acknowledged that REACH appears inconsistent in excluding polymers from registration but requiring monomers in polymers to be registered. The issue was referred to the European Court of Justice.

Evaluation. The next stage following registration is the evaluation procedure, which consists of evaluation of dossiers and substances. Dossier evaluation is automatic where animal testing is proposed. Substance evaluation is the process through which the regulatory authorities decide whether deeper assessment of a substance is warranted and consider what further information needs to be provided by the industry. Substance evaluation must be carried out when technical data submitted by registrants raises doubts in the regulators' mind as to the risks of some substances. Substances identified for evaluation will be allocated, on a rolling basis, to a Member State, which will act as rapporteur. Where the original doubts are confirmed, further risk-management actions may be prompted, such as the inclusion of the substance on the list of substances subject to authorisation or the drafting of adequate risk-reduction measures, which, in turn, may lead to further risk management actions under the restriction or authorisation procedures.

Authorisation. Substances of very high concern are subject to authorisation. This is probably the most controversial aspect of REACH. Following a specific sunset date, the Commission's approval is required before substances of very high concern may be produced, placed on the market, and/or used. Applicants have to show that the risk posed by those substances is adequately controlled or that the socio-economic benefit from their use is greater than the risk. These substances (to be listed in Annex XIV of the REACH Regulation) are to be progressively replaced by suitable alternatives, provided it is technically and economically possible. On 30 June 2008, the ECHA published the first list of chemicals to be potentially classified as substances of very high concern. The authorisation process commences in 2010.

After the submission of applications for authorisation, the ECHA must arrange for the scientific review of the technical file and risk assessment and, on the basis of its findings, draft a recommendation for the Commission. EU Member States are involved in the process through a permanent Member State committee under the ECHA's auspices. The Commission may authorise substances of very high concern subject to review and monitoring. As the burden of proof for chemicals deemed too dangerous to be placed on the market until proven otherwise is placed on manufacturers and importers, it is expected that manufacturers, importers, and downstream users of chemicals of very high concern will seek safer alternatives and substitutes where possible.

The authorisation procedure stretches the boundaries of risk regulation into a more advanced precautionary zone. REACH represents an important step towards the application of the precautionary principle within a broad policy context.

Restrictions. Restrictions on the production, marketing, and use of dangerous substances are alternatives to authorisation. Any substance on its own, in preparations, or in articles may be subject to restrictions if the risk posed needs to be addressed on a community-wide basis. This is the ultimate stage where the risk to human health and the environment is regarded as unacceptable. Annex XVII of the REACH Regulation contains the list of restricted substances.

Exemptions. As REACH's objective is to support innovation, there are a number of exemptions from the new chemicals regime, such as substances covered by other equivalent EU legislation. Substances for scientific experimentation and chemical research carried out under controlled conditions are exempt from registration if their volume is below one tonne per year. However, restrictions and authorisations may apply to substances in volumes below one tonne per year. Process-orientated research and development benefits from the exemption from registration under Directive 67/548/EEC, without interruption, provided the ECHA was notified by 16 May 2008.

The practical impact of REACH depends on the ECHA's diligence in reviewing applications, evaluating substances, and making recommendations upon which the Commission will base its decisions. It is after a first group of applications for authorisation have been processed and decided upon that REACH's effectiveness as a system of risk control can be assessed. To achieve its purpose, the authorisation process must succeed in preventing dangerous substances from being manufactured, used, or placed on the market. REACH's effectiveness will also depend on its enforcement, as the previous chemical regime was plagued by inadequate enforcement.

REACH's impact is not limited to manufacturers and importers of chemicals. Although faced with limited obligations, downstream users must ensure that any substance used in their processes is pre-registered, authorised for its intended use, and available from 1 December 2008. The financial burden of compliance will be substantial for companies and is likely to prove too challenging for smaller companies. In addition, REACH could stir a new flow of product liability claims, in the both the EU and the United States, as information on the hazards of certain substances is released into the public domain.

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