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REACH: New Community Legal Framework for Chemicals

On 1 June 2007, Regulation (EC) No. 1907/2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) took effect. The REACH Regulation gradually replaces several existing Community directives and regulations on chemicals and sets a comprehensive Community legal framework for use of chemicals. By strengthening the reporting and evaluation obligations of producers, importers and downstream users, and by setting new mechanisms for enforcing their compliance, the REACH Regulation mainly aims to improve protection of human health and the environment from thousands of chemical substances used by the industry, and to improve the way the internal market functions.

The REACH system is based on the principle that it is not the public authorities, but manufacturers, importers and downstream (industrial) users (e.g., manufacturers of articles containing chemical substances) who must ensure that they manufacture, place on the market or use substances that do not adversely affect human health or the environment. The fulfilment of the obligations of all the parties must further reflect the precautionary principle underpinning the system. REACH has a very wide scope, covering all chemical substances with the exception only of those specifically mentioned in the Regulation.

"REACH is a complex system which sets obligations for a great number of entities operating on the Internal Market."

Registration

EU manufacturers and importers of chemicals in quantities of or above one tonne per year are obliged to register the substances with the new European Chemicals Agency based in Helsinki. Substances are divided between the so-called "phase-in substances" (listed in the European Inventory of Existing Commercial Chemical Substances or manufactured in the Community in the last 15 years) and "non-phase-in substances" (not produced or marketed before 1 June 2007). In general, the registration takes place ex ante, i.e., a substance must be registered before being manufactured, imported or used by the industry. However, phase-in substances will be logically registered by existing manufacturers, importers and

downstream only ex post, in deadlines (phases) set by the Regulation (from 2010 to 2018) and depending on the quantity of the manufactured/imported/used substance. In order to benefit from these transitional deadlines for registration of phase-in substances, the respective entities must pre-register with the Agency before 1 December 2008.

It should be stressed that chemicals, not preparations or articles containing the chemicals, are subject to the registration. Producers or importers of articles containing substances are to register if the quantity of the substance used is 1 tonne per year or above, and if the substance is intended to be released from the articles during normal and reasonably foreseeable conditions of use. For articles containing substances of very high concern (carcinogenic, mutagenic, toxic, etc.), the Regulation sets a special notification procedure.

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Only EU manufacturers/importers/downstream users are subject to the REACH legislation. However, instead of importers, the obligations related to importation of substances from outside the EU can be fulfilled by the non-EU manufacturers through their qualified EU-based representatives. Importers of their substances will thus be released from their registration obligations and will instead be regarded as downstream users of the registered substance.

Within the registration, registrants need to provide the Agency with necessary information on the manufactured/imported/used substances and assess risks connected with their production or use. The registration must contain a technical dossier with information on the properties, uses, classification of the substance and guidance on safe use. For substances in quantities above 10 tonnes, a chemical safety report must also be submitted describing the hazards and an assessment of whether the substance is of high concern (persistent, bioaccumulative, toxic, etc.). In some cases, the report must also describe exposure scenarios, including the appropriate risk management measures ensuring that the risks ensuing from use of the substance are adequately controlled.

Efficient use of available data should minimise the need for testing on animals. The registration costs for both registrants and the Agency should also be reduced to the necessary minimum by efficient exchange of data. Where possible, registrants should submit the principal information on one and the same substance jointly. In other cases, they should contact previous registrants based on references from the Agency and use the previously gained data in exchange for payment.

Information obligations and obligations of downstream users

All the involved parties are obliged actively to provide, both down and up the supply chain, necessary information relating to properties of substances, risks and risk management measures. Information on dangerous substances is to be transmitted by a safety data sheet, a form already in use by the industry. Downstream users are obliged to apply appropriate risk management measures and only those uses of substances covered by the safety data sheet, or to perform their own chemical safety assessment for other uses.

Evaluation

The Agency will continuously check the completeness of registration dossiers. Furthermore, to prevent unnecessary animal testing, the Agency will be checking registrants' testing proposals and deciding on the means of their execution. Finally, based on the reported properties and tonnage of a substance, the Agency and the Member States will be setting Community rolling action plans selecting substances to be evaluated each year.

Authorisation

The Agency, the European Commission and the Member States will gradually build up a list of substances of very high concern (Annex XIV substances, such as carcinogenic, mutagenic, toxic, and others). A decision on inclusion of a substance in Annex XIV will indicate a date from which using the substance and making it available will be allowed only subject to a person- and use-specific authorisation issued by the Commission. An authorisation will be generally granted if the applicant can demonstrate a sufficient level of control of identified risks, or if the socio-economic benefits outweigh the risks and there are no suitable alternative substances or processes. Authorisations can be modified and withdrawn anytime, depending on new data available and identification of new substitutes.

Restrictions

Annex XVII of the Regulation contains a list of substances that present an unacceptable risk to the health or the environment. The substances listed in Annex XVII on their own, in a preparation or in an article, shall not be manufactured, placed on the market or used unless in compliance with the general conditions of restriction set in the Annex.

What now and what then

REACH is a complex system which sets obligations for a great number of entities operating on the Internal Market. Given the approaching commencement date of application of most of the procedures under REACH (1 June 2008), we recommend all involved stakeholders begin acquainting themselves with the Regulation and identify their role and obligations in the system. The outcomes of the REACH Implementation Projects (RIPs) led by the European Commission and guidance issued by the Agency should help the stakeholders to get orientated in the processes and obligations.

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