



# EU Analyst: Environment & Life Sciences

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### 1. "REACH" CHEMICALS CONTROL REGULATION ADOPTED

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#### Overview

In December 2006 agreement was reached on the new EU chemicals regulatory regime. Contained in [Regulation \(EC\) No. 1907/2006](#), concerning the Registration, Evaluation and Authorisation of Chemicals ("REACH"), it comprises 141 Articles and 17 Annexes, covering a total of 849 pages. It is mammoth in its concept, in its detailed rules and in the burden for parties in the supply chain who must comply. It is expected to affect the placing on the EU market of some 30,000 chemical substances, imposing major administrative responsibilities and costs on EU producers and importers of these substances. Downstream users, including producers of finished articles incorporating these substances, will be significantly affected as well.

The key elements of REACH are summarised below but a detailed examination in its entirety is essential to ensure that all steps are taken to comply with the various requirements within the applicable deadlines, and of course to ensure ongoing compliance. Manufacturers or importers cannot place a substance onto the EU market unless it is registered in a timely fashion and, if necessary, has secured authorisation (the "no data, no market" principle). This prohibition also concerns use of substances by EU

downstream users and by non-EU producers who want to export products containing a given substance to the EU. Everybody in the supply chain must be aware of how REACH can affect their operations and ensure that all requirements are fulfilled up and down the supply chain. *REACH will enter into force on 1 June 2007*, meaning that suppliers and users must actively prepare themselves. *Steptoe will shortly be announcing a one day seminar devoted to practical compliance with REACH (in Washington, with access by telephone for those who cannot be present). If you wish to be notified of further information on this conference please e-mail [events@steptoe.com](mailto:events@steptoe.com).*

#### REACH policy objectives

The central policy objective is to transfer responsibility for the generation of data on the safety of chemical substances from governmental authorities to the parties placing them on the EU market. This objective covers substances used on their own, in preparations or incorporated into finished articles. Placing on the market means supplying or making available to a third party, whether for payment or free, including importation into the EU. Another key objective is transparency, to be achieved initially by requiring registration with the newly established European Chemicals Agency (the "Agency") of all chemical substances placed on the market; registration will entail submission of detailed information about the substance, its uses, related risks and guidance on safe use. Transparency also entails making certain (non-confidential) information available throughout the supply chain as well as to final consumers, e.g., concerning certain dangerous substances ("substances of very high concern") in the finished products they purchase.

#### Registration by manufacturers/importers

The registration of substances manufactured or imported in quantities of 1 tonne or more, whether on their own, in preparations or finished articles or as intermediates, is the fundamental requirement of REACH. What specific information has to be submitted for the registration, and when the

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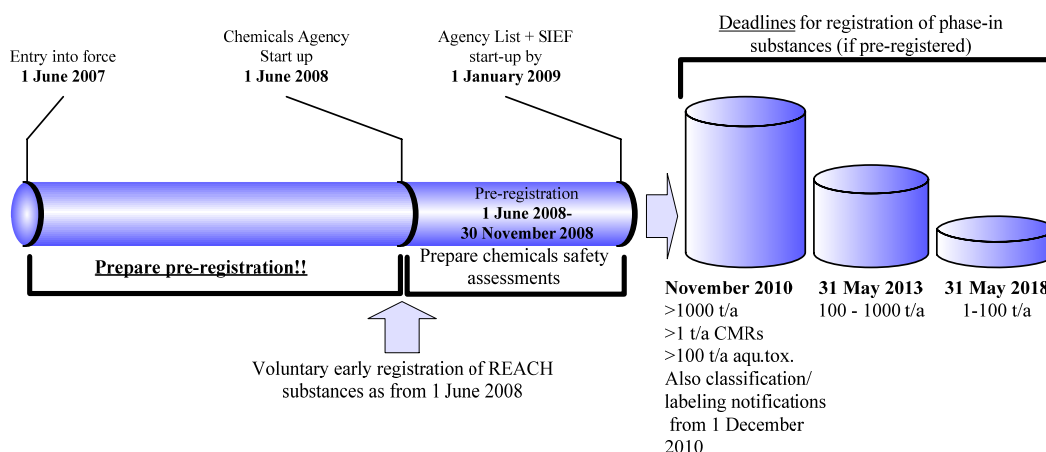
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registration must be made, depend on the hazard of the substance in question and the volume manufactured or imported (summarised below). The Regulation provides for transitional registration periods for so-called “phase-in” substances (mainly substances listed in the European Inventory of Existing Commercial Chemical Substances – [EINECS](#)) according to the volumes manufactured or imported but *only if the substances in question are pre-registered between 1 June and 1 December 2008*.

Downstream users (“DUs”) of a substance that have not been pre-registered may ask the Agency to extend the pre-registration period by 6 months to give them time to find a supplier or to pre-register the substance themselves. DUs are defined as any EU natural or legal entity that uses a substance in the course of its industrial or commercial activities, excluding distributors and consumers. The Agency must publish a list of the pre-registered substances by 1 January 2009 and DUs can see from the list whether the substance of concern has been pre-registered or not. If properly pre-registered, the transitional *deadlines for registration of phase-in substances* are:

- 30 November 2010 for phase-in substances i) manufactured or imported (“M/I”) in quantities  $\geq 1,000$  tonnes per year per manufacturer or importer, ii) substances classified as very toxic to the aquatic environment and M/I in quantities  $\geq 100$  t/a per manufacturer or importer, and iii) substances classified as carcinogenic, mutagenic or toxic to reproduction (“CMRs”) M/I in quantities  $\geq 1$  t/a per manufacturer or importer.
- 31 May 2013 for phase-in substances M/I in quantities between 100 and 1000 t/a per manufacturer or importer.
- 31 May 2018 for phase-in substances M/I in quantities between 1 and 100 t/a per manufacturer or importer.

## Essential Dates for REACH Compliance



Substances that must be registered but which miss the pre-registration period cannot benefit from the above transitional deadlines and become subject to the “no registration, no market” rule, i.e., the party is barred from placing the substance on the EU market pending proper registration.



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The data required for pre-registration is not extensive (name of substance including CAS and EINECS number, contact body, foreseen deadline for registration and tonnage band). However, many companies will have substantial work to identify all of their substances (substances on their own, all substances in preparations, substances in finished products) that are subject to the REACH registration requirements and to ready the files for the pre-registration. Each substance needs to be individually pre-registered.

## Content of registrations

All registrations must include, at minimum, the “technical dossier”. The technical dossier will include the identity of the manufacturer/importer, identity of the substance, information on the manufacture and use(s) of the substance, the classification and labelling of the substance, exposure information, and guidance on safe use. Study summaries (or robust study summaries in specified cases) must also be provided concerning information derived from testing required under Annexes VII to XI – the level of testing required varies according to the tonnages manufactured or imported (e.g., the most extensive testing applies for substances M/I in quantities  $\geq 1,000$  t/a). If further testing is needed, proposals must be submitted first.

In addition, chemical safety assessments and a chemical safety report (“CSR”) are required for substances M/I in quantities  $\geq 10$  t/a. The CSR sets out the hazards and classification of the substance and whether it is persistent, bioaccumulative and toxic (“PBT”) or very persistent, very bioaccumulative (“vPvB”). The CSR must also provide exposure scenarios, including recommendations for measures to ensure that risks to humans and the environment are adequately controlled, regarding the registrant’s own uses and all uses identified by DUs in the chain. If the assessment is required but a DU does not notify its use to its supplier/registrant or uses a substance outside the conditions covered in the registrant’s CSR, the DU itself must perform the safety assessment concerning its uses.

## Data and cost sharing

Given the extent of data that must be generated for an individual registration, the Regulation provides for sharing of data, tasks and costs. The above-noted pre-registration of phase-in substances, for example, results in establishment of a Substance Information Exchange Forum (“SIEF”) for each substance. Each SIEF will group all intended registrants of the particular substance (manufacturer, importer, potentially also DUs or other holders of information on the substance) and enable them to share certain information and determine, for example, which studies are available and/or still need to be carried out. Owners of full study reports are required to permit reference to existing vertebrate testing reports and, if requested, also concerning non-vertebrate testing reports. The SIEF parties must agree on generation of any required new testing. Costs for testing must be shared fairly. Fines might be imposed if a study owner refuses to provide either proof of the cost of its study (for purposes of cost sharing and, upon payment, granting permission for the other party to refer to the full study report in its own registration) or the study itself.

In the case of non-phase-in substances and registrants of phase-in substances who have not pre-registered, each potential registrant must inquire to the Agency if a registration has already been submitted for the substance in question. If so, it will be put in contact with previous registrants in order that information and costs can be shared if necessary in order to make the registration.

Also to help reduce registration costs, the Regulation provides that certain data (e.g., on hazardous properties of the substance and classification) should normally be submitted jointly. Thus, a “lead registrant” would submit the data with the agreement of the other registrants. Specified other data must be individually submitted. Certain data, including the CSR, can be submitted jointly but nonetheless might be submitted separately if, for example, this would result in disclosure of commercially sensitive

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information or a joint submission would be disproportionately costly to the company in question.

## Substances in articles

A special regime applies concerning substances contained in articles. "Articles" includes finished products ranging from clothing, marking pens and toys to air conditioners, computers and vehicles. Clearly, many articles placed on the EU market contain a large number of substances that are subject to REACH, with some of these substances being potentially dangerous if released from the article during its use.

REACH requires that all substances *intended to be released* from articles during normal and reasonably foreseeable conditions of use (e.g., ink from cartridges) must be *registered* by the producer or importer according to the normal REACH rules (including pre-registration, volume deadlines and information rules) if those substances are present in the articles above 1 t/a per producer or importer.

In addition, the producer or importer must *notify* the Agency and provide certain specified information for each substance in the article that meets the "substances of very high concern" ("SVHC") criteria *and* is identified in the "candidate list" of substances considered by the Agency to meet the SVHC criteria *if 3 conditions apply*: (i) the substance is present in those articles in quantities totalling over 1 t/a per producer or importer, (ii) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w), and (iii) the producer or importer cannot exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use of the article including disposal. Upon the notification, the Agency can further require full registration of any substance in the article if the volume criterion is met and the Agency "has grounds for suspecting" that the substance is in fact released and presents a risk to humans or the environment.

Note that these provisions on registration/notification of substances in articles do not apply to substances that have already been registered for that use.

Importantly, non-EU manufacturers can appoint a single natural or legal person in the EU to fulfil the REACH obligations that must otherwise be carried out by each importer in the manufacturer's supply chain; in that case the actual importers are deemed to be DU.

## Authorisation of SVHC

Annex XIV of REACH will comprise a list of substances determined to be of very high concern in respect of human and environmental safety. Substances to be listed in Annex XIV are those which meet the criteria set out in Article 57, including CMRs, PBTs, vPvBs as well as certain other substances, such as endocrine disrupters, for which there is scientific evidence of probable serious effects "which give rise to an equivalent level of concern". A producer, importer or downstream user can only place a substance on the market which is included in Annex XIV if, *inter alia*, the use(s) of that substance on its own or in a preparation or the incorporation of the substance into an article has been properly authorised.

Applications for authorisation can be made by one or several parties, can cover one or several substances if they are part of the same group and can concern one or multiple uses (own uses and/or uses intended downstream). The application must include an analysis of potential alternative substances (including any relevant R&D undertaken by the applicant) and, if suitable alternatives exist, a substitution plan including a timetable for actions proposed by the applicant.

The provisions on authorisation criteria distinguish between the different hazard classifications and situations where safety thresholds can or cannot be determined. In general, authorisations will be granted if the risk to humans/environment is "adequately controlled". However, more restrictive conditions apply concerning (i) CMRs and certain other SVHC for which safety thresholds are not possible to determine, (ii) PBTs and vPvBs, and (iii) other SVHC identified as having PBT or vPvB properties. In these cases, authorisation can be granted only if it is shown that socio-economic benefits outweigh the risk to human health or the environment and there are no suitable

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alternative substances or technologies. In this context, consideration will be given to, *inter alia*, the information submitted by the applicant and/or other parties concerning alternatives.

Decisions on suitability of alternatives will take into account technical and economic feasibility for the applicant and whether substitution would actually result in reduced overall risks. When granted, authorisations will be subject to time-limited reviews determined on a case-by-case basis and normally subject also to conditions, such as monitoring.

## Information in the supply chain

Suppliers of substances and preparations must provide recipients with safety data sheets ("SDS") whenever a substance or preparation is classified as dangerous, is a PBT or vPvB or is listed in the candidate list for substances requiring authorisation for other reasons. Instances are also specified for when an SDS is required or not. Importantly, REACH requires any supplier of an article containing a SVHC to provide recipients (at no cost) with available information to allow safe use including, at a minimum, the name of the substance. Also in these circumstances the supplier must provide the same information to any consumer who requests it.

## Classification and labelling inventory

Any manufacturer, producer of articles or importer who places a substance requiring registration on the market must provide information to the Agency to enable it to compile, and keep updated, a classification and labelling inventory that will be publicly accessible. The obligation to supply this information will apply from 1 December 2010.

## Action items

It is evident that REACH imposes significant and complex obligations on all parties placing chemical substances onto the EU market, whether on their own, in preparations or in finished articles. This overview is necessarily brief and incomplete. It is essential for companies to understand all of the requirements

applying to them and their supply chain and to prepare to comply, including:

- Prepare an inventory of substances placed on the EU market as a manufacturer and/or importer (substance on its own, in preparation or in article) (possible multiple roles within same group)
- Verify REACH requirements for each substance and sufficiency of own data on each substance having regard to total data needed per the volume band of registrant and substance classification (note some substances may be exempt from registration requirements but not other information requirements)
- Anticipate REACH SIEFs per substance and how to meet own and other parties' data needs (sharing of existing data/costs, generation of necessary new tests/data; joint registration criteria)
- Consider partnerships/consortia to manage data/cost sharing and protection of confidential business information; if non-EU manufacturer, decide whether to use "single representative"
- Identify other parties in the supply chain and respective REACH responsibilities and confirm that each intends to comply (DUs particularly to confirm registration/authorisation upstream for your uses)

Finally, the Commission will publish technical guidance documents for industry in early-mid 2007 and roll out new software packages to facilitate compliance, but preparatory measures can and should already be undertaken. Our experience in assisting companies to understand and achieve compliance with other EU substance control regulations (e.g. hazardous substances in electrical and electronic products) confirms that early action is crucial.

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