The REACH of EU chemical rules

Peter Bogaert and Cándido García Molyneux, Covington & Burling LLP

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Since June 2007, manufacturers, importers and suppliers of medicinal products, medical devices, foods and cosmetics must comply and closely monitor the requirements of the EU's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH). REACH imposes rigorous requirements that are additional to EU product-specific vertical legislation.

REACH is characterised by the following features:

- REACH shifts the burden of proof from regulators to producers by imposing the principle of "no data, no market". It requires producers to know the substances that are contained in their products, their properties and to prove that the products are safe.
- REACH assumes the existence of an information chain starting with the substance's manufacturer and ending with the final supplier, the retailer of the finished product. REACH requires each party in the supply chain to gather and share information on the substances contained in their products, and imposes different obligations on them based on the information they are assumed to have. All members of the chain must closely monitor REACH compliance of their suppliers and customers, and significantly improve communication with them. This increased communication and co-operation, however, also triggers new anti-trust and confidentiality concerns.
- REACH establishes fast-track procedures for the phasing out of particular dangerous substances on the basis of the precautionary principle. Target substances include so-called "substances of very high concern" (SVHCs):
  - category 1 and 2 carcinogens, mutagens and toxic to reproduction substances (CMRs);
  - persistent, bioaccumulative and toxic substances (PBTs);
  - very persistent and bioaccumulative substances (vPvBs); and
  - substances raising an equivalent level of concern.

  REACH also allows the European Commission (Commission) to ban, under the so-called "restrictions" procedure, any substance posing an "unacceptable risk" to human health or the environment.

These phase out and restriction procedures are accompanied by the regulatory discretion provided by REACH (that the European Court of Justice tends to confirm), to the European Chemicals Agency (ECHA) and the Commission.

Against this background, this article sets out the key aspects of the regulatory framework set out in REACH, in particular:

- The main REACH requirements.
- Medicinal products.
- Food and feedingstuffs.
- Medical devices.
- Cosmetic products.
- Packaging.
- Legal entities, foreign manufacturers, Only Representatives and third party representatives.
- SIEFS, data sharing and consortia.

THE MAIN REACH REQUIREMENTS

REACH imposes different requirements on substances on their own, in preparations or in finished articles, and depending on whether they are manufactured in, or imported into, the EU/European Economic Area (EEA). Preparations are defined as mixtures or solutions of two or more substances, such as toothpastes, foods, dental filing materials, most medicines, lubricants, shaving creams and contact lens solutions. Articles are objects that are given a special shape, surface or design during production, which determines their function to a greater degree than their chemical composition. Examples of articles include cardiac pace makers, catheters and razors.

REACH will progressively introduce a set of key requirements (*see box, Timetable for introduction of REACH requirements*).

While REACH contains broad exemptions for medicinal products, food and feedingstuffs, manufacturers, importers and suppliers of medical devices and cosmetic products are likely to be subject to virtually all REACH obligations.

MEDICINAL PRODUCTS

REACH has different impacts on:

- Medicinal products in the finished state for the final user.
- Medicinal products in bulk.
- Active substances and excipients that are intended to be used in medicinal products (without any chemical transformation).

TIMETABLE FOR INTRODUCTION OF REACH REQUIREMENTS

As of June 2007. Supply of safety data sheets to professional customers

Suppliers of individual substances or products in preparations must provide their professional customers with safety data sheets if:

- Their supplied substances or preparations are classified as dangerous under the Directive 67/548/EEC (Dangerous Dangerous Substances) or the future Regulation on the Global Harmonised System.
- The supplied substance meets the criteria of a PBT or vPvB substance, or is later identified as a SVHC.
- On request of their customers, preparations contain substances classified as dangerous, PBTs or vPvBs, substances that are identified as a SVHC, or substances subject to workplace exposure limits, in concentrations above specified thresholds.

This information will allow manufacturers of medicines, cosmetics, foods and medical devices to learn more about the properties of the substances they use and, on that basis, assess the applicable REACH requirements.

As of 1 June 2008. Registration of substances manufactured or imported in quantities of one ton or more per manufacturer/importer per year

All manufacturers and importers of substances on their own, in products in the form of preparations, and in some cases articles, must register the substances they manufacture or import in quantities of one ton or more per manufacturer/importer per year, unless an exception applies. Registration will require submitting a:

- Technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will involve substantial testing and data gathering.
- Chemical safety report assessing the hazards, exposure and risks of use during the entire life cycle for substances manufactured or imported in quantities of ten tons or more per manufacturer or importer per year. Registration will be substance and company specific. Only chemical manufacturers and importers that register will be allowed to manufacture or import, and therefore supply, their substances or products containing them.

Importers and manufacturers of articles (that is, objects) intended to release substances can also be required to register the releasing substances if all of the following thresholds are met:

- The substances are present in articles in quantities exceeding one ton per manufacturer per importer per year.
- The substances are intended to be released during normal or reasonably foreseeable conditions of the article's use.
- The use of the substance in articles is not already registered by any third party.

Examples of articles intended to release substances include intelligent packaging releasing preservatives and razors with comfort strips.

A limited number of substances are exempt from registration. These include polymers (but their monomers may be subject to registration), and substances and categories of substances listed in Annexes IV and V to REACH. Non-isolated intermediates are also exempt from registration, while isolated intermediates may benefit from limited registration requirements under certain conditions.

- Intermediates and processing aids that are used in the manufacture of active substances and excipients of medicinal products.
- Investigational products used in clinical trials.

Medicinal products in finished state

All substances contained in finished medicinal products intended for final users are exempt from most REACH requirements, including registration, downstream user requirements, evaluation, information through the supply chain, and authorisation of SVHCs. This exemption is also likely to apply to medicinal products intended to be marketed in third countries.

However, any substance contained in medicinal products may be subject to REACH marketing and use restrictions unless the specific entry for each restricted substance specifies otherwise.

Medicinal products in bulk

Substances contained in medicinal products (in their pharmaceutical form) but in bulk (such as pills in bulk that are not yet placed in the final packaging) are also exempt from the REACH requirements of registration, downstream users, evaluation, and authorisation. This exemption is also likely to apply to medicinal products intended to be marketed in third countries.

However, substances in medicinal products in bulk will normally be subject to REACH information through supply chain