

REACH: **Part 1 of a 2-Part Feature**

Do you know your RIPs from your SIEFs?

The new European law on chemicals, REACH (Registration, Evaluation, Authorisation and Restriction of Chemicals) entered into force on 1 June 2007.

A short history

Feb 2001	White Paper on 'Strategy for a future Chemicals Policy'
May 2003	Internet consultation: 6000+ comments received
Oct 2003	Commission adopts REACH proposal
Dec 2006	Council and Parliament adopt amended REACH proposal in Second Reading of co-decision procedure
30.12.06	REACH is published in the Official Journal
RIPs	REACH implementation Projects
SIEFs	Substance Information Exchange Fora

Timings

REACH entered into force on 1 June 2007 as the start of a process that is planned to last at least 11 years and is likely to last considerably longer.

The principle milestones for the next 11 years are summarised below: -

- **1 June 2007:** REACH entry into force;
- **1 June 2008 – 30 November 2008:** Period for pre-registration by manufacturers and importers (registrants) of the phase-in substances they intend to register according to the various phase-in deadlines. Generally, phase-in substances are those listed on EINECS (the European Inventory for Existing Chemical Substances);
- **30 November 2010:** Registration deadline for registrants supplying a pre-registered phase-in substance above 1,000 tonnes per year, or a CMR cat.1 or 2 substance above 1 tonne per year, or an R50-53 substance (Persistent and liable to Bioaccumulate and Toxic (PBT) / very Persistent and very Bioaccumulative (vPvB) above 100 tonnes per year;
- **31 May 2013:** Registration deadline for registrants supplying a pre-registered phase-in substance above 100 tonnes per year;
- **31 May 2018:** Registration deadline for registrants supplying a pre-registered phase-in substance above 1 tonne per year.

Summary

The aim of REACH is to improve the protection of human health and the environment through the better and earlier identification of the properties of chemical substances. At the same time, innovative capability and competitiveness of the EU chemicals industry should be enhanced. The benefits of the REACH system will come gradually, as more and more substances are phased into REACH.

The REACH Regulation introduces a shift in responsibilities from public authorities towards industry. REACH gives greater responsibility to industry to manage the risks from chemicals and to provide safety information on the substances. Manufacturers and importers will be required to gather information on the properties of their substances, which will help them manage them safely, and to register the information in a central database. The European Chemicals Agency will act as the central point in the REACH system: it will run the databases necessary to operate the system, co-ordinate the in-depth evaluation of suspicious chemicals and run a public database in which consumers and professionals can find hazard information.

REACH applies to the manufacture, import, placement on the market and use of substances, with certain exceptions.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

Why REACH?

REACH replaces about 40 pieces of legislation with a streamlined and improved Regulation. Other legislation regulating chemicals (e.g. on cosmetics, detergents) or related legislation (e.g. on health and safety of workers handling chemicals, product safety, construction products) not replaced by REACH will continue to apply. REACH has been designed not to overlap or conflict with the other chemical legislation.

How will REACH work?

REACH makes industry bear most responsibilities to manage the risks posed by chemicals and provide appropriate safety information to their users.

In parallel, it foresees that the European Union can take additional measures on highly dangerous substances, where there is a need for complementing action at EU level. REACH also creates the *European Chemicals Agency (ECHA)* with a central co-ordination and implementation role in the overall process.

All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market. For substances produced or

imported in quantities of 1 tonne or more per year per company, manufacturers and importers need to demonstrate that they have appropriately done so by means of a registration dossier, which shall be submitted to ECHA – The Agency. Once the registration dossier has been received, the Agency may check that it is compliant with the Regulation and shall evaluate testing proposals to ensure that the assessment of the chemical substances will not result in unnecessary testing, especially on animals.

Where appropriate, authorities may also select substances for a broader substance evaluation to further investigate substances of concern.

REACH also foresees an authorisation system aiming to ensure that substances of very high concern are adequately controlled, and progressively substituted by safer substances or technologies or only used where there is an overall benefit for society of using the substance. These substances will be prioritised and over time included in Annex XIV. Once they are included, industry will have to submit applications to the Agency on authorisation for continued use of these substances. In addition, EU authorities may impose restrictions on the manufacture, use or placement on the market of substances causing an unacceptable risk to human health or the environment.

Manufacturers and importers must provide their downstream users with the risk information they need to use the substance safely. This will be done via the classification and labelling system and Safety Data Sheets (SDS), where needed.

Substances can be exempted from all or a part of the obligations under REACH. These exemptions are not described in detail on the ECHA web-site (About REACH). More information on exemptions can be found when using the ECHA web-site navigator. Companies are strongly advised to use the navigator to find out if their substance is covered by an exemption under REACH.

Why REACH will be important to your company?

REACH will impact chemical use and supply globally and the withdrawal of substances from your supply chain is inevitable. REACH will produce both costs and benefits, plus it will create opportunities as well as threats.

The provision of a greater level of information could affect liability and many importers into the EU, their agents and customers will require scientific and technical help.

Be careful! If your company imports the chemical from outside the EU, you are considered as an importer and NOT as a downstream user.

Need for new 'Cultural Change' approach

Most safety health and environment legislation is largely 'technical' in nature and usually is delegated to HSE departments and professionals, But, REACH is different, companies and organisations will have to think in a

fundamentally different way - across all their operations. If your chemicals have no data, then you have no market.

Perhaps they will have to rewrite the marketing handbooks, because under REACH pre-manufacture and testing is essential before you can go to market. Meeting a customer's requirement will take on a new approach for each new product (article). The onus will be on industry, not the regulator to ensure new products are pre-tested even before you know if you can sell it and whether it meets the customer requirements.

The role of the regulators / authorities will be 'one step' removed. There will be greater sharing of information on substances in products (preparations and articles), there will be forced co-operation between companies (data sharing) and forced communication along the supply chain (properties, identified uses, risk management).

Business decisions will feed into technical areas and vice versa (used to support, relationship with customers and suppliers) and there will be legal considerations (how to work together, confidentiality, supply contracts). Contracts covering joint 'confidential' work will be the norm. REACH is a continuous process and all its obligations will be here to stay.

GUIDANCE WILL BE PROVIDED TO ENSURE REACH OBLIGATIONS ARE FULFILLED.

Guidance has been developed over the past few years for industry and the authorities for a smooth implementation of REACH. The guidance documents were drafted and discussed within projects led by the European Commission services, involving stakeholders from Industry, Member States and non-governmental organisations.

Finalised guidance documents are published on the ECHA website. They are detailed documents and LUBE Magazine readers may wish to download those applicable to their activity. Use the LINKS at the end of this feature.

National Competent Authorities

National helpdesks will be established in each Member State to provide advice to industry on their obligations and how to fulfil their obligations under REACH, in particular in relation to registration. *From my research it seems that new substances and existing substances could be handled by different agencies in some EU Member States.*

The UK helpdesk is already up and working, see the HSE website for details.

<http://www.hse.gov.uk/reach/compath.htm>

The others are listed opposite: -

EU New Substances Authorities

ECB, European Chemicals Bureau
<http://ecb.jrc.it/new-chemicals>
DG Environment
<http://ec.europa.eu/environment>
Manual of Decisions
http://ec.europa.eu/environment/dansub/home_en.htm

EU National Competent Authorities

Austria

Bundesministerium für Land-und Forstwirtschaft, Umwelt und Wasserwirtschaft
<http://www.umweltbundesamt.at>

Belgium

Ministère des Affaires sociales, de la Santé Publique et de l'Environnement
<http://www.oecd.org/ehs/NewChem/be-nc.htm>
http://www.environment.fgov.be/Root/organisation/risinfo_nl.htm

Bulgaria

Ministry of Environment and Water
http://www.moew.government.bg/index_e.html

Cyprus

Labour Inspection Officer
Ministry of Labour and Social Insurance
Department of Labour Inspection
http://www.mlsi.gov.cy/mlsi/dli/dli.nsf/dmlindex_en/dmlindex_en?OpenDocument

Czech Republic

Ministerstvo Zdravotnictví CR
<http://www.mzcr.cz>

Denmark

Miljøministeriet Miljøstyrelsen
<http://www.mst.dk>

Estonia

Chemicals Notification Centre
<http://www.ktk.ee/>

Finland

The National Product Control Agency for Welfare & Health
<http://www.sttv.fi>

France

Ministère de l'Environnement
<http://www.ecologie.gouv.fr/sommaire.php3>
INRS, Institut National de recherche et de Sécurité
<http://www.inrs.fr>

Germany

Bundesministerium für Umwelt, Naturschutz und Reaktorsicherheit.
<http://www.bmu.de>
Bundesanstalt für Arbeitsschutz und Arbeitsmedizin (BAuA)
<http://www.baua.de/amst>

Greece

Ministry Of Finance
State General Chemical Laboratory
Division of Dangerous Substances and preparations

Hungary

National Institute of Chemical Safety, Hungary
<http://efirk.antsz.hu/okk/okbi>

Ireland

Health and Safety Authority
<http://www.hsa.ie>

Italy

Istituto Superiore Di Sanità
<http://www.iss.it>

Latvia

Latvian Environment Agency
<http://www.lva.gov.lv>

Lithuania

Environmental Protection Agency
Department of Chemical Substances
<http://www.infochema.lt>

Luxembourg

Ministère de l'Environnement
<http://www.mev.etat.lu/ra96/et1.html>

Malta

Malta Standards Authority
Director - Foodstuffs, Chemicals & Cosmetics
<http://www.health.gov.mt>

Netherlands

Ministry of Housing, Spatial Planning and the Environment
<http://www.minvrom.nl>
National Institute for Public Health and the Environment,
Chemical Substances Bureau
<http://www.rivm.nl/bms>

Poland

Inspektor do Spraw Substancji
I Preparatów Chemicznych
<http://www.bip.gov.pl/index.asp?fid=4419>

Portugal

Direcção-Geral Do Ambiente
<http://www.iambiente.pt>

Romania

Romanian Ministry of Environment & Water Management
<http://www.mmediu.ro/home/home.php>

Slovenia

National Chemicals Bureau
<http://www2.gov.si/mz/mz-splet.nsf>

Slovakia

Centre for Chemical Substances and Preparations
<http://www.cchlp.sk>

Spain

Ministerio de Sanidad y Consumo
<http://www.msc.es/salud/ambiental>

Sweden

National Chemicals Inspectorate
<http://www.kemi.se>

United Kingdom

HSE, Health and Safety Executive
<http://www.hse.gov.uk/reach/compauth.htm>

Norway

SFT, Norwegian State Pollution Control Authority
<http://www.sft.no>

Determine what actions your company needs to take

Each company will need to assess what actions they should be taking with regard to REACH, taking into account whether they are manufacturers, importers, downstream users, etc. Some substances may be withdrawn, so companies should start taking steps to cover that situation, should it happen. Some suggested first steps are shown below. This list is not definitive, but precise actions will depend on each company's circumstances.

- Form a REACH Task Force for your company and agree its terms of reference
- Quantify what impact REACH will have on your business
- Prioritise your resources
- Identify all substances that you manufacture and your customers, both existing and potential
- Supply chain mapping: identify all purchased substances that are used as components in your manufacturing and their supplier(s)
- Identify substances (those you manufacture or import) that you need to pre-register
- Identify those substances you want to ensure your supplier will pre-register
- Research alternative substances and their potential suppliers and make provision for uncertainty of key supplies
- Produce a plan for the introduction of new and updated safety data sheets (SDS)
- Ensure your company improves communication up and down the supply chain
- Regularly report progress to management

The Detail: REACH Implementation Projects (RIPs)

The aim of the REACH Implementation Projects (RIPs) is to ensure an efficient implementation of the new legislation through the development of guidance documents and IT-tools for the European Chemicals Agency, for industry and the authorities of the Member States.

The European Chemicals Bureau (ECB) has the main practical experience for administering the practical implementation of the pre-REACH chemicals legislation. Therefore, they have been given the responsibility of developing those tools and methodologies; however close collaboration with DG ENV and DG ENTR will ensure the political and legislative compatibility.

The RIPs include 8 areas:

- RIP 1 – REACH Process description
- RIP 2 – REACH-IT: Development of the IT system to support the REACH implementation
- RIP 3 – Technical Guidance: development of tools for industry**
- RIP 4 – Technical Guidance: development of tools for authorities
- RIP 5/6 – Setting up the Agency
- RIP 7 – Preparation of the new tasks for the commission
- RIP 8 – Agency Standard operational procedures

For many LUBE readers, the most important RIP will be RIP 3 and its sub-sets

RIP 3 - Guidance Documents

RIP 3 REACH Process Guidance, essential for industry, is broken down into many guidance sub-sections documents. The following list only shows the main sub-sets, there are others that may be relevant to your activity.

RIP 3.1: Guidance on Registration: **Preparing the registration dossier.**

RIP 3.2: Guidance on preparing the **Chemical Safety Report (CSR).**

RIP 3.2.2: Technical Guidance Document (TGD) on preparing CSR, subdivided into 5 Tasks

RIP 3.3: Guidance on **Information Requirements** on Intrinsic Properties of substances.

RIP 3.4: Guidance on **Data sharing** (Pre-registration).

RIP 3.5: Guidance on **Downstream-User** Requirements.

RIP 3.6: Guidance on **Classification and Labelling under Global Harmonised System.**

On hold until proposal for implementing GHS is adopted by the Commission.

RIP 3.7: **Guidance on preparing an Application Dossier for Authorisation.**

RIP 3.8: Guidance on fulfilling the **Requirements for articles** (Substances in Articles).

RIP 3.9: Guidance on carrying out a **Socio-Economic Analysis** or input for one.

RIP 3.10: Guidance for Identification and Naming of Substances in REACH.

See LUBE-TECH 54 for Part 2 of the Feature