

# REACH REGULATION



## Ready to help with all of your REACH needs Questions & Answers

The complexity of REACH has meant that many questions are being asked. Here we hope to answer some of those questions most commonly asked.

### **What are the key dates within the Regulation?**

*1 June 2007* - REACH enters into force.

*1 June 2008* - The European Chemicals Agency (ECHA) officially becomes operational.

*1 June 2008 to 30 November 2008* - Pre-registration of "phase-in" substances takes place.

*1 January 2009* - The ECHA releases the official list of chemicals requiring registration.

*30 November 2010* - The registration deadline for substances manufactured/imported in quantities  $\geq 1,000$

tonnes per year, as well as carcinogens, mutagens and substances toxic to reproduction (CMR categories 1 & 2) manufactured/imported in quantities  $\geq 1$  tonne per year and substances classified as very toxic to aquatic organisms (R50/53)  $\geq 100$  tonnes per year.

*31 May 2013* - The registration deadline for substances manufactured/imported in quantities  $\geq 100$  tonnes, but less than 1,000 tonnes per year.

*31 May 2018* - The registration deadline for substances manufactured/imported in quantities  $\geq 1$  tonne, but less than 100 tonnes per year.

It should also be understood that voluntary registration can commence from **1st June 2008** and that new

substances must be registered before they can be manufactured/imported. These can also be registered from **1st June 2008**.

### **What are considered to be the most dangerous substances under REACH?**

Of the highest concern are carcinogens, mutagens, substances that are toxic to reproduction, persistent, bio-accumulative and toxic substances (PBT's), very persistent and very bio-accumulative substances (vPvB's) and those substances identified from scientific evidence as causing equivalent concern to any of those mentioned above. An example would be substances that disturb the hormone system (endocrine disruptors).

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#### **What is the purpose of the European Chemicals Agency?**

The European Chemicals Agency (commonly referred to as the "ECHA") is located in Helsinki, Finland, and was created to initially oversee the introduction of REACH.

Additional duties will include ensuring consistency at Community level in relation to technical, scientific and administrative aspects of REACH and, occasionally, may carry out some of these tasks itself. The ECHA is also expected to provide EU Member States with the best scientific and technical advice on questions relating to the chemicals covered by the regulation.

#### **Do I have to pre-register?**

There is no obligation to pre-register, but should you fail to do so your products can no longer be exported to the EU from 1st December 2008, and this will remain in force until the products have been registered. It would effectively mean you would register alone, and you would be responsible for all costs arising from registration, which is a very expensive procedure.

By pre-registering you will benefit from the staggered registration dates, cost-share with other registrants and be able to access certain data from within SIEF's.

#### **We manufacture yarns for the textile industry that are exported to the EU. Do we need to register?**

Amongst the most affected articles exported to the EU are textiles.

Yarns may contain preservatives and dyes that might unintentionally be released during wearing or washing and so these substances will almost certainly have to be notified and, on the basis of this notification, then have to be registered.

Taking this into consideration it is recommended that pre-registration is carried out.

#### **Our articles are packaged for their protection during transit to our customers in the EU. Do we have to take any action on the packaging materials?**

Packaging materials are articles under REACH, so the same obligations apply to the packaging materials as do for the articles itself which are packaged.

#### **Are we obligated to register plastics?**

No, polymers are exempt from REACH, however the **monomers** making up a polymer must be registered.

#### **We export products to Norway, but as Norway is not a member of the EU we do not therefore have to register our products.**

Whilst it is correct to say that Norway is not a member of the EU, it is actually a member of the European Economic Area (EEA) which also includes Iceland and Liechtenstein. The EEA nations have adopted REACH, so any product destined for these three countries must also be registered. The same applies to Monaco, Guadeloupe, French Guiana, Martinique and Réunion, which are all considered as overseas départements of France.



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#### Are batteries covered under REACH?

Yes, batteries contain chemical substances so are therefore covered under REACH.

Technical Guidance notes have been published which set out that a car battery is considered to be an article under REACH, however as there is no intended release of the chemical substances during "normal operation" there is no requirement to register them.

It should be noted that some substances used in batteries (lead, nickel, cadmium, lithium, etc.) may be classed as Substances of Very High Concern (SVHC's) and will therefore have to be **notified**. Lead may also be subject to an **authorisation** from the ECHA.

#### We manufacture products that are exported to the EU - should we appoint an Only Representative to register on our behalf?

Appointing an Only Representative (OR) to act on your behalf should be given close consideration before any decision is made.

You should ask yourself whether your EU customers have the ability to pre-register and that they possess sufficient knowledge of REACH. For your customers to register you must provide them with sensitive intellectual property and must therefore be confident that this information can be properly protected. What would happen to this information if your supply agreement expired and was not subsequently renewed?

Finally, can your customers afford the financial costs of registration, do they have adequate resources available and can they carry out the preparatory work in good time? Many SME's find

REACH a frightening proposition and are already searching for EU manufactured products rather than continue purchasing from non-EU sources.

Appointing an OR automatically classifies your EU customers as **Downstream Users**, lessening the impact and obligations of REACH on them.

#### Can a laboratory located outside of the EU conduct toxicological and ecotoxicological tests for REACH?

Yes it is possible for these laboratories to conduct tests, but on certain conditions.

A laboratory is required to follow the Good Laboratory Practice (GLP) Principles as developed by the Organisation for Economic Co-operation & Development (OECD), and which have been incorporated into current EU legislation. Additional to GLP, it would be helpful for non-EU laboratories to adopt other quality accreditation, such as ISO/IEC 17025:2005, although ISO 9001:2000 or EFQM could be equally acceptable.

For laboratories that are not located within OECD member nations it is still possible for them to receive GLP status. Nations such as India have become observers to the OECD Working Group on GLP and members of the OECD Test Guidelines Programme. Laboratories in such countries may then request inspection by the monitoring authority of an OECD country in order to receive GLP status.



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**Article** – An object which, during production, is given a specific shape, surface or design that determines its function to a greater degree than does its chemical composition.

**Authorisation** – Required for the placing on the market for a use and for the use itself of substances of very high concern (SVHC) which are included in Annex XIV of the REACH Regulation. In this list, the following substances may be included: substances with CMR 1&2, PBT and/or vPvB properties and substances with an equivalent level of concern, such as those having endocrine disrupting properties.

**CMR** – Substances which present at least one of the following properties: Carcinogenic, Mutagenic or Toxic for reproduction.

**CSA** – Chemical Safety Assessment.

**CSR** – Chemical Safety Report.

**Consortium** – When a pre-registered substance is to be registered by two or more manufacturers/producers and/or importers, certain information of the technical registration dossier shall first be submitted by a "lead-registrant" acting with the assent of the other registrants. Only under certain conditions a registrant can submit a separate registration. The registrants may decide whether jointly or separately to submit certain other information of the technical dossier and the chemical safety report.

Furthermore, regarding studies necessary to meet information requirements for registration purposes, those studies involving testing on vertebrate animals must be shared and other studies shall be shared among registrants. The

data sharing between registrants is set out in order to avoid unnecessary testing on vertebrate animals and to limit the duplication of other tests.

**Distributor** – Any natural or legal person established within the European Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

**DU** – Downstream User. Any natural or legal person established within the European Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or consumer is not a downstream user. A re-importer exempted from the registration obligations, the special obligations of downstream users and obligations in connection with evaluation shall be regarded as a downstream user.

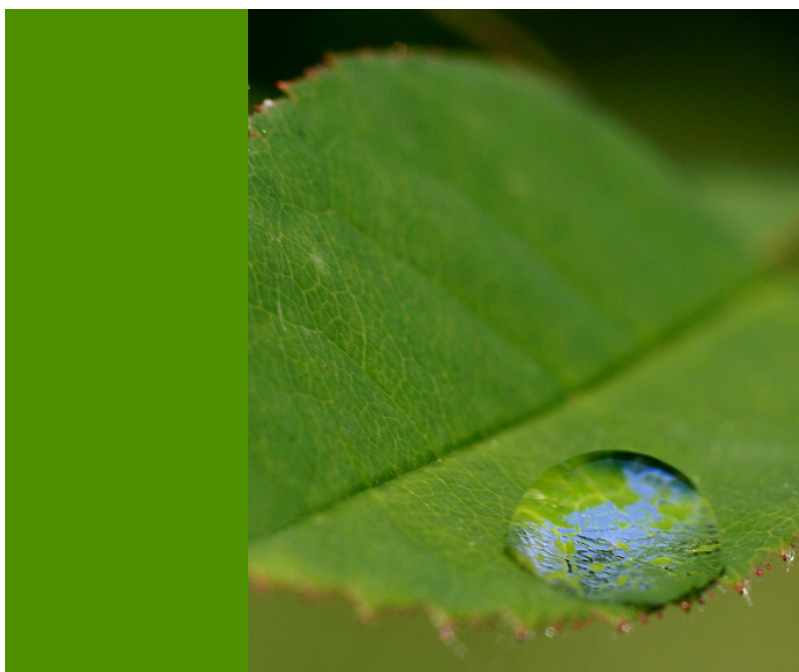
**ECB** – European Chemicals Bureau.

**ECHA** – European Chemicals Agency, to be established in Helsinki, Finland.

**EIF** – Entry Into Force.

**EINECS** – European Inventory of Existing Commercial chemical Substances. A list of > 100,000 substances deemed to be on the European Community market on 18th September 1981.

**ELINCS** – European List of Notified Chemical Substances. A list of > 4,000 notified substances not contained in EINECS.



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**ES** – Exposure Scenario. The set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer/importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate.

**Evaluation** – Dossier evaluation to examine testing proposals set out in a registration or a downstream user report and to randomly check compliance of registrations with information requirements. Substance evaluation to test information on a substance for the risks of the substance to human health or the environment.

**Existing Chemicals/Existing Substances** – Substances listed in EINECS.

**GLP** – Good Laboratory Practice. Ecotoxicological and toxicological tests and analyses for the generation of intrinsic properties of substances shall be carried out in compliance with the principles of good laboratory practice provided for in Directive 2004/10/EC or other international standards recognised as being equivalent by the Commission or the Agency and with the provisions of Directive 86/609/EEC, if applicable.

**Import** – The physical introduction into the customs territory of the European Community.

**Importer** – Any natural or legal person established within the European Community who is responsible for import.

**Intermediate** – A substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereto referred to as “synthesis”).

**IUCLID** – The International Uniform Chemical Information Database. This is the basic tool for the collection of data and evaluation in the frame of the European Risk Assessment Programme on Existing Substances.

**IUCLID5** – A software tool intended for use by industry, ECHA and EU Member State Competent Authorities for REACH purposes.

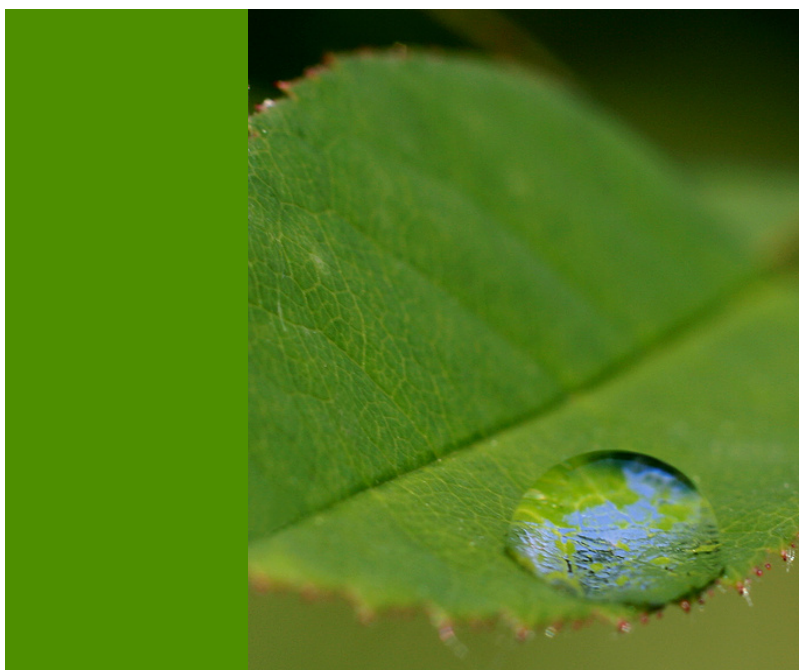
**IUPAC** – International Union of Pure and Applied Chemistry.

**IUPAC Nomenclature** – A system of naming chemical compounds established under the auspices of IUPAC.

**Manufacturer** – Any natural or legal person established within the European Community who manufactures a substance within the Community.

**New Chemicals/New Substances** – Chemical substances not listed in EINECS. Notified new chemicals are listed in ELINCS.

**PBT** – Substances which are Persistent, Bioaccumulative and Toxic.



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**Phase-In Substance** – A substance that (i) is listed in the European Inventory of Existing Chemical Substances (EINECS); or (ii) was manufactured in the European Community, or the countries acceding to the EU on 1st January 1995 or 1st May 2004, but not placed on the market by the manufacturer or importer, at least once in the fifteen years before the entry into force of the REACH Regulation, provided the manufacturer or importer has documentary evidence of this; or (iii) was placed on the market in the European Community, or in the countries acceding to the EU on 1st January 1995 or 1st May 2004, before entry into force of the REACH Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in the REACH Regulation, provided the manufacturer or importer has documentary evidence of this.

**Placing On The Market** – Supplying or making available to a third party (against payment or free of charge). Import into the customs territory of the European Community is considered “placing on the market”.

**Preparation** – A mixture or solution composed of two or more substances (e.g. paint, detergent, cosmetics).

**Producer of an Article** – Any natural or legal person who makes or assembles an article within the European Community.

**QSAR/(Q)SAR** – Quantitative Structure Activity Relationship – Theoretical models on quantitative

relationships which under REACH can under certain conditions be used instead of testing to generate information on dangerous properties of substances.

**REACH** – Registration, Evaluation, and Authorisation and restriction of Chemicals (also termed Registration, Evaluation, Authorisation of Chemicals).

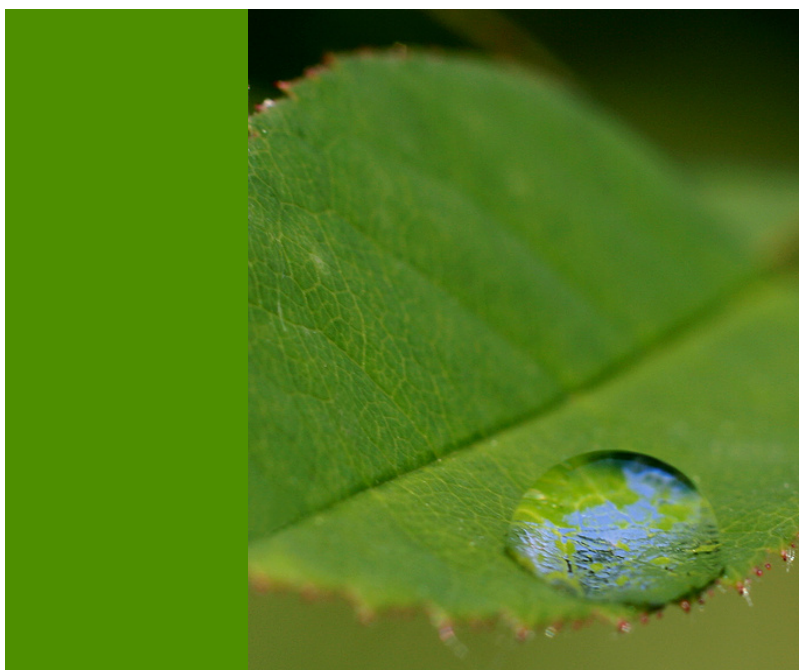
**Registrant** – The manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance.

**Release Of Substances** – Substances in articles are subject to registration if (i) the substance is intended to be released under normal or reasonably foreseeable conditions of use and (ii) the substance is present in quantities totalling over 1 tonne per year.

**RIP's** – Reach Implementation Projects. The European Chemicals Bureau (ECB) has the responsibility of developing methodologies, tools and technical guidance needed for REACH through a number of RIPs. The aim of the RIPs is to ensure an efficient implementation of the future legislation through the development of guidance documents and IT-tools for the new Agency, for industry and the authorities of the Member States.

**RMM** – Risk Management Measures.

**SAR** – Structure Activity Relationship – Theoretical models on qualitative relationships which under REACH can under certain conditions be used instead of testing to generate information on dangerous properties of substances.



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**SDS** – Safety Data Sheet.

**Substance** – A chemical element and its compounds, in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent, which may be separated without affecting the stability of the substance or changing its composition.

**SIEF** - Substance Information Exchange Forum.

**SME** - Small and Medium sized Enterprise.

**SVHC** - Substance of Very High Concern (CMR 1&2, PBT, vPvB...).

**TGD** – Technical Guidance Document.

**Use** – Any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation.

**vPvB** – Substances that are very Persistent and very Bioaccumulative.

