



Basic Information Guide to REACH



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Introduction

The European Commission issued a proposal for a Regulation on the Registration Evaluation and Authorisation of Chemicals (REACH) on 29 October 2003. This proposal for the radical overhaul of legislation on chemicals is based on the need to upgrade the existing legislative system for the control of chemicals manufactured and imported in the European Union, which is considered to be inefficient and slow. There is also a common public perception that the existing system does not provide enough information on human health and environmental effects.

At present there are more than 40 pieces of legislation covering chemicals placed on the market in Europe. These control how chemicals are tested, labeled, assessed, marketed and restricted. However this legislation only came into force after 1981 and as a result there is limited health & safety information on the majority of chemicals placed on the market.

In order to address this, the REACH Regulation was proposed which would impose specific obligations not only on manufacturers and importers of chemicals but also on their customers and downstream users from all sectors and industries. REACH aims to make these people responsible for understanding and managing the risks associated with the use of chemicals.

On the 1st June 2007 this regulation will come into force. The Health and Safety Authority are responsible for implementing this European Regulation in Ireland. It is very important that industry are aware of the regulations and their obligations under it. This guide aims to explain the basic structure and give an overview of the regulation.

What is REACH?

The aim of the proposed REACH regulations is to replace the current 40 pieces of legislation with a single, coherent legislative system for new and existing chemicals.

The basic elements of the Regulation are:

- Industry must register all existing & future new substances of quantities of 1 tonne or more per year, with a new European Chemicals Agency
- Existing substances have to be registered within the first 11 years (the phase in period)
- These substances are prioritised based on volume produced or imported into the EU on an annual basis

The stages involved in REACH are as follows;

- **Registration** of substances produced or imported in volumes greater than 1 tonne per year.
- **Evaluation** of testing proposals and data provided to Agency and Member States under the registration procedure and evaluation of substances with potential risks, which may lead to the authorisation and restriction procedures.
- **Authorisation** of specific uses of substances of high concern.
- **Chemicals** includes chemical substances, chemical preparations, substances in articles e.g. ink in an ink jet

REACH also includes other steps such as:

- **Restriction** - Will provide for the conditional use or a ban on the use of substances that pose unacceptable risks,

- **Classification and Labeling inventory** - All chemicals will need to be classified and labeled before being placed on the market

A core objective within REACH is the promotion of sustainable development by creating a balance between economic, social and environmental concerns. In other words, it hopes to improve protection of human health and the environment while enhancing the competitiveness of European Industry.

Why is REACH being put in place?

The current legislative system for chemical management is deemed to be inadequate due to;

- Lack of information on effects to human health and environment from chemicals, especially those chemicals that were on the market prior to September 1981 (so-called Existing Substances, listed on EINECS, the European Inventory of Existing Chemical Substances)
- Where risks were identified, the legislation is slow to assess them and introduce risk management measures
- Burden of proof is presently placed on public authorities

Who will REACH impact?

Examples of products and industrial sectors likely to be affected both directly and indirectly by the proposed regulations include:

Table 1

Products	Industry Sectors
Aerosols	Aeronautic Industry
Adhesives, Sealants, Silicones	Agriculture
Agricultural Chemicals,	Aquaculture
Fertilisers	Automotive Industry
Animal Feedingstuffs	Chemical blenders and Importers
Biocides	Construction Industry
Coatings, Paints, Varnishes	Cosmetic Industry
Cosmetics	Defence
Detergents, Surfactants	Dry cleaning
Food Additives	Electronics and electrical industry
Food Colourings and	Food industry
Flavourings	Glass, Optical Manufacturers
Industrial Gases	Healthcare
Inks	Hygiene and Cleaning Product Manufacturers
Inorganic chemicals	Maintenance Activities, e.g. Paint shops,
Leather Treatment Chemicals	Motor Repairs, Man-made Fibres
Medicines	Marine Industry, Mechanical Workshops
Organic Chemicals	Medical Devices, Metal Workshops
Pesticides	Mining and Extraction
Petrochemicals,	Packaging and Labels manufacturers
Oleochemicals	Pest Controllers, Pharmaceuticals
Pharmaceuticals	Photographic Industry
Photographic Chemicals	Plastic, PVC, Plastic Component
Pigments, Dyes	Manufacturers

Rubber, Plastics and Polymer Related Products Solvents, Lubricants	Printing Pulp and Paper Semi-conductors Telecommunications, Cable Manufacturers Textiles Toys Utilities – Energy Production, Water Treatment, Waste Recycling, Transport
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As the table above shows REACH will have an affect on all businesses and industries in some shape or form. For Ireland the majority of the industries above will be hit with an increase in the cost of chemicals or products which contain certain chemical substances that they may use.

The Steps of REACH

1. Pre-Registration

Manufacturers or importers (M/I) must pre-register substances that are already on the EU Market (Phase-In Substances), if they want to benefit from transitional arrangements. These arrangements allow the company a number of years before the full technical dossier of the substance needs to be submitted.

CMR 1 & 2 (≥ 1 t/a), ≥ 1000t/a & R50 – 53 (≥ 100 t/a)	1st Dec 2010
≥ 100 t/a	1st June 2013
≥ 1 t/a	1st June 2018

Pre registration also enables registrants to share data with other registrants in Substance Information Exchange Forums (SIEF) thus avoiding the need to carry out redundant tests.

NB: Pre registration is limited to the period from 1st June 2008 till December 2008.

If the M/I does not pre register their substances in this time period, it must register their substance without delay. They will also not be able to avail of the support of the SIEFs.

2. Registration

This is the basis of REACH and is required for all substances with a manufacturing or importing volume of one tonne per year or more, substances in articles if present in >1 tonne and are dangerous and intended for release.

There are some exemptions in the registration process;

- Product and Process Orientated Research and Development (PPORD) is exempted from Registration for 5 (+ 5) years
- Polymers are exempted from registration; however the Commission has committed to consider how polymers can be addressed in the future
- Intermediates benefit from reduced requirements

For registered substances manufacturers and importers will have to gather physicochemical, toxicological and ecotoxicological properties and produce a **Technical Dossier**. For larger quantities of substances some animal testing may be required, however at this stage the registrant will only need to have written proposals of these tests. The information required for the technical dossier is outlined in Annex II of this document.

If a substance is manufactured or imported in volumes of more than 10 tonnes/year then a **Chemical Safety Report (CSR)** is required. A CSR provides information on all the identified uses of the substance. The CSR also contains a **Chemical Safety Assessment (CSA)** which will assess the risks to human health and the environment associated with those uses and what control measures should be put in place.

2.1 Data Sharing

As mentioned before pre-registration is set up to facilitate data sharing and so reduce testing on vertebrate animals and to reduce costs to industry. For both phase-in and non-phase-in substances, data gained by vertebrate animal testing are to be shared, in exchange for payment. Communication mechanisms are set up to enable manufacturers and importers to reach agreements on the sharing of studies on vertebrate animals. Information not involving tests on vertebrate animals (e.g. in vitro studies and QSARs) must be shared on the request of a potential registrant.

For phase-in substances, a system is established to help registrants to find other registrants with whom they can share data and to get an overview about which studies are available (pre-registration). Pre-registrants of the same phase-in substance are then required to share existing vertebrate animal test data as well as other information and agree on the generation of new test data in a Substance Information Exchange Forum (SIEF).

Downstream users of a substance that has not been pre-registered may ask the Agency to extend the pre-registration period by six months to give them more time to find a supplier or pre-register the substance themselves.

2.2 Communication in the supply chain

REACH foresees communication in the supply chain in two directions:

Communication down the supply chain (from suppliers to customers)

Suppliers of substances must pass on information on the health, safety and environmental properties and safe use of their chemicals to their downstream users. This is done via a Safety Data Sheet (SDS). The manufacturer, importer or downstream user will prepare the SDS according to a similar principle as he did before REACH came into force. The main difference is that when required, the SDS will also have an annex including exposure scenarios specifying the conditions under which the substance or preparation can be used safely, for uses that have been identified.

If an SDS is not required, the supplier shall still communicate key risk information about the substance, in particular stating if the substance is subject to authorisation or restriction, together with any other available and relevant information to enable appropriate risk management. Furthermore, suppliers of articles shall inform their customers about substances of very high concern contained in concentrations above 0.1%. Also, consumers can request such information.

Communication upstream (from customers to suppliers)

Upstream communication by an actor in the supply chain is mandatory in a number of situations. This includes the communication of new information on the hazardous properties that become available as well as of information that may call into question the appropriateness of the risk management measures recommended by the supplier. Distributors have a general obligation to pass on information received to the next actor in the supply chain.

Downstream users have a right to make their use known to the supplier and in doing so shall provide sufficient information to prepare an exposure scenario. This upstream communication will play an important role when a registrant will prepare a chemical safety report, including exposure scenarios if required, as a part of the registration dossier. The manufacturers and importers often do not know what the substance is used for, and how it is used, and therefore need to collect such information from customers in order to assess how risks can be adequately controlled for the different identified uses. The downstream users have on the other hand the detailed knowledge on their uses and also an interest in having these covered by the suppliers' exposure scenarios thus being able to continue the use and receiving relevant information on how to control possible risks.

Manufacturer/importer must to cover all uses identified by downstream users in their Chemicals Safety Report.

However for confidentiality reasons a downstream user can decide not to disclose the use of certain substances. In that case, the downstream user must carry out the assessment himself and prepare its own Chemical Safety Report, for those uses outside the conditions described in an exposure scenario.

3. Evaluation

Evaluation provides a means for the authorities to require registrants, and in limited cases downstream users, to provide further information

There are two types of evaluation; Dossier and Substance.

Dossier Evaluation

Evaluates testing proposals (as outlined in the registration dossier) to avoid duplication of animal testing. Checks compliance with registration requirements of the Regulation. This is performed by the Agency.

Substance Evaluation

Is performed when there is a reason to suspect that a substance presents risks to human health and the environment. All registration dossiers submitted for a substance are examined together and any other available information is taken into account. This is coordinated by the Agency but conducted by the Member States.

The outcome of an evaluation may be that the registrants have to provide additional information either to bring their registration into compliance or to help clarify risks.

4. Authorisation

Substances of very high concern will be gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used unless the company is granted an authorisation for a specific use.

Substances of very high concern include substances which are:

- Carcinogenic, Mutagenic or toxic to Reproduction (CMR) classified in category 1 or 2,
- Persistent, Bioaccumulative and Toxic (PBT) or very Persistent and very Bioaccumulative (vPvB) according to the criteria in Annex XIII of the REACH Regulation, and/or
- identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case and on the basis of scientific evidence, such as endocrine disrupters.

Annex III of this document provides a step by step guide as to how these substances of high concern will be regulated.

5. Restrictions

The restriction procedure is a safety net for substances posing an unacceptable risk to human health or the environment arising from its manufacture, use or placing on the market, which need to be addressed on a Community wide basis.

- A restriction of a substance is any condition for, or prohibition of, its manufacture, use or placing on the market.
- Restriction of a substance can apply to all uses or just to specific uses
- The Agency or MS can prepare a dossier in accordance with Annex XV of the Regulation to propose restrictions. They must demonstrate that the manufacture, placing on the market or use of a substance on its own, in a preparation or in an article poses a risk to human health or the environment that is unacceptable and that the risk needs to be addressed at Community level.

6. Substances in Articles

For substances in articles, a special regime applies regarding registration and notification under REACH. An article is the legal term under REACH for any object that has been given a specific shape, surface or design so that it can be used for a specific purpose (e.g. manufactured goods such as cars, textiles, electronic chips).

REACH requires all substances that are intended to be released from articles during normal and reasonably foreseeable conditions of use to be registered according to the normal rules, if they are produced or imported in quantities exceeding 1 tonne/year per producer or importer. In addition, all substances included in a 'candidate list', which are present in articles above a concentration limit of 0.1% weight by weight and above 1 tonne per year must be notified to the Agency.

Such notification is not required, however, when exposure to humans and environment can be excluded during normal conditions of use, including disposal. In that case safety instructions should be provided.

A notification of a substance in an article consists of sending a dossier to the Agency containing the identity of the notifier, the identity of the substance, its classification and labelling, a brief description of its use and the tonnage range.

As a safety net, the Agency can require a registration of a substance in an article at any time if it considers that the release of the substance poses a risk to human health or the environment.

7. Classification & Labelling Inventory

This section concerns notification to the Agency and the classification and labelling of substances when placing them on the market. The regulation builds on the established system for classification and labelling and prepares the ground for the introduction of the Globally Harmonised System.

Industry is required to submit all its classifications to the Agency, so that they can be included in the classifications inventor. This is to be done by the end of 2010.

Annex 1

Definitions – Words used throughout the REACH Regulation

Agency: a central Agency will be in charge of the day-to-day management of the system

Article: manufactured product that has a final shape that is related to its use e.g. car.

Competent Authorities: the authority or authorities or bodies established by the member states to carry out their obligations arising from the REACH system.

Downstream User: uses a substance either on its own or in a preparation, in the course of his industrial or professional activities. Not a distributor or a consumer.

Distributor: Any legal or natural person, including a retailer, who only stores and places on the market a substance, on its own or in a preparation for a third party.

Exposure Scenarios: Expose scenario means a set of conditions, including operational conditions and risk management measures, that is concerned with control measures.

Identified Use: Any use of a particular substance that the registrant has been made aware of. Downstream users have the right to demand from their suppliers to register substances for all their uses

Importer: responsible for importing into the community (the 27 EU member states)

Intermediates: a substance that is solely manufactured for and consumed in or used for chemical processing to be transformed into another substance

- (a) *non-isolated intermediate* – during synthesis it is not intentionally removed from the equipment.
- (b) *on-site isolated intermediate* – an intermediate not meeting the criteria for a non-isolated intermediate and it is manufactured or used on the same site
- (c) *transported isolated intermediate* – intermediate that is transported and supplied to other sites.

Manufacturer: manufactures a substance within the community

Phase-In Substance: means a substance which, over the 15 years preceding the entry into force of this Regulation, meets at least one of the following criteria;

- (a) it was manufactured in or imported into the Community (now includes accession states), by a manufacturer or importer and is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS)
- (b) it was manufactured in the Community (now includes accession states), but not placed on the market by the manufacturer or importer
- (c) it was placed on the market in the Community (now includes accession states), and between 18 September 1981 and the 31 October 1993 inclusive it was also placed on the market 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, as amended by Directive 79/831/EEC, but does not meet the definition of a polymer set out in Directive 67/548/EEC, as amended by Directive 92/32/EEC, provided the manufacturer or importer has documentary evidence of this.

Polymer: a substance consisting of molecules characterised by the sequence of one or more types of monomer units.

Preparation: a mixture or solution composed of 2 or more substances

Registrant: Registrant means the manufacturer or importer of a substance or the producer of an article submitting for registration of a substance.

Substance: Substances means 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 use, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition.

Annex 2

Technical Dossier Information Requirements

- Identity of manufacturer or importer, identity of substance
- Information about manufacturing process and quantity produced, including all identified uses
- Classification and labelling information
- Guidance on safe use (storage, disposal, first aid measures)
- All relevant and available test data (including a literature search) but as a minimum “robust study summaries” of test data (Annexes VII-X)
- Proposal for additional tests
- Exposure information for 1-10 tonnes
- Indication as to which information has been reviewed by an independent assessor
- Request for confidentiality in accordance to article 118 (2)

Annex 3

Authorisation of substances of very high concern

There is no tonnage threshold for a substance to be subject to authorisation. The authorisation process consists of four steps. Industry has obligations in the third step. However, all interested parties have the opportunity to provide input in steps 1 and 2.

Step 1: Identification of substances of very high concern (by authorities)

This will be done by Member State authorities or the Agency (on behalf of the European Commission) by preparing a dossier in accordance with Annex XV. Interested parties can comment on substances for which a dossier has been prepared. The outcome of this identification process is a list of identified substances, which are candidates for prioritisation (the “candidate list”). The list will be published by the Agency, probably not before end-2008.

Step 2: Prioritisation process (by authorities)

The substances on the candidate list are then prioritised to determine which ones should be subject to authorisation. Interested parties are invited to submit comments during this process. At the end of the prioritisation process, the following decisions are taken:

- whether or not the substance is subject to authorisation;
- which uses of the included substances will not need authorisation (e.g. because sufficient controls established by other legislation are already in place);
- the “sunset date” by when a substance can no longer be used without authorisation.

Step 3: Applications for authorisation (by industry)

Applications for authorisation need to be made within the set deadlines for each use that is not exempted from the authorisation requirement. They must include:

- a chemical safety report covering risks related to those properties that caused the substance to be included in authorisation system (unless already submitted as part of the registration);
- an analysis of possible alternative substances or technologies including, where appropriate, information on research and development foreseen or already in progress to develop such alternatives.

If an applicant’s chemicals safety report demonstrates adequate control of risks, and the analysis of alternatives reveals that there is a suitable alternative, the applicant must submit a substitution plan, explaining how and when he intends to replace the substance by the alternative. A suitable alternative is an alternative that results in reduction of overall risks and is technically and economically feasible for the applicant.

In cases where the applicant is not able to demonstrate adequate control of risks and where no suitable alternative exists, he needs to include in his application a socio-economic analysis.

A fee has to be paid for each application.

For all applications, the Agency will provide expert opinions. The applicant can comment on these opinions.

Step 4: Granting of authorisations (by the European Commission)

Authorisations will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled. The “adequate control route” does not apply for substances for which it is not possible to determine thresholds and substances with PBT or vPvB properties.

If the risk is not adequately controlled, an authorisation may still be granted if it is proven that the socio-economic benefits outweigh the risks and there are no suitable alternative substances or technologies.

Downstream users may only use such substances for uses which have been authorised.

For this they must either:

- obtain the substance from a company that was granted an authorisation for that use. They must stay within the conditions of that authorisation. Such downstream users must notify the Agency that they are using an authorised substance.
- apply themselves for authorisations for their own uses.

Reviews

All authorisations will be reviewed after a certain time-limit which will be set on a case-by-case basis.