



A brief introduction to the European Commission's regulatory proposal on Registration, Authorisation and Evaluation of Chemicals (REACH)

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This briefing outlines the REACH regulation as proposed by the European Commission [1] on 29th October 2003. It is not a comprehensive guide to REACH; it offers an introduction to some of the main features, and suggests further sources of information.

1. Introduction to REACH

REACH is designed to be an integrated approach to the control of the production, import and use of chemicals in Europe. It intends to create a system which is based on information about chemicals, and which ensures that useful safety information gets to those using chemicals. The REACH system is quite complex, though so are the network of 40 or so regulations that it is replacing.

Crucially, in REACH the main responsibility for chemical safety is clearly placed on the chemical producer, not on public authorities or downstream users.

REACH can be thought of as fulfilling two key roles:

- it lays out the regulatory system that will be in place when it is fully implemented (around 2018), when all chemicals on the market produced or imported at 1 tonne or more per annum are registered with safety data, and there is no longer a backlog of chemicals for which there is insufficient safety information.
- it describes the phased process to overcome the backlog of a lack of safety data on

chemicals – including an 11 year period for registering safety information on existing chemicals.

This briefing outlines the scope of the provisions of REACH, and which chemicals are affected by which provisions. Different parts of the regulation have differing scope – for example, a substance may not need to be registered, but could be subject to restrictions if evidence of a problem emerged.

The briefing splits REACH into the following (based on the structure of the regulation itself):

- **Definitions** – what is a substance? Or an intermediate?
- **Substances totally exempted from REACH** – a few substances are totally outside REACH
- **Registration** – The process under which chemical producers will be obliged to send a registration dossier containing safety data to a central chemicals agency on chemicals produced or imported in quantities of one tonne per year or above. This provision includes a phase in period of 11 years in order to collect this information for the 'existing chemicals'.
- **Evaluation** – Member State experts will evaluate this safety data for certain chemicals, in particular those produced at higher volumes and those of particular concern. This may lead requests for further information to clarify risks, or ensure compliance with the

requirements; to MS deciding to propose the substance for ‘authorisation’ or ‘restrictions’; or no further action.

- **Authorisation** - Chemicals deemed to be of very high concern will be subject to authorisation, which first identifies and prioritises the chemicals, and then allows industry to submit a case for their continued use. Chemicals of very high concern are defined as those that are carcinogens; mutagens; reproductive toxins; are persistent, bio-accumulative and toxic; very persistent and very bio-accumulative; and of similar concern, e.g. endocrine disrupters.
- **Restrictions** – Chemicals with other properties of concern (e.g. toxic to the nervous system) may have their uses controlled through this system.
- **Agency** – A new European Chemicals Agency will be created in Helsinki.
- **Classification and labeling** – REACH creates a new inventory of classification and labeling.
- **Information flow** – Much, though not all, of the information generated by REACH will be publicly available.

REACH is a major reform of chemicals management in Europe. It is not yet finalized, but it is unlikely that major changes will be made at this stage, though minor changes are likely.

The REACH proposal is currently being discussed by the European Parliament and the EU Member States, with entry into force currently estimated to be in the first half of 2007.

For a much more detailed explanation of how REACH works, with many flowcharts, see the Commission’s process description [2]. The Commission has also published a detailed, question and answers paper on REACH [3]. Both Environment and Enterprise departments have REACH web sites:

<http://europa.eu.int/comm/environment/chemicals/reach.htm>

<http://europa.eu.int/comm/enterprise/reach/index.htm>

2. Definitions

REACH is concerned with the production and use of substances and preparations, and, to some

extent, the use of substances in articles. Some key definitions (taken from the text) are:

- “*Substance* means a chemical element and its compounds in the natural state or obtained by any manufacturing process,…” [This paper – and much discussion on REACH – often uses the word ‘chemical’ rather than ‘substance’, but a substance can also sometimes be a mixture, e.g. a crude oil fraction]
- “*Preparation* means a mixture or solution composed of two or more substances” [e.g. paint]
- “*Article* means an object composed of one or more substances or preparations which during production is given a specific shape, surface or design determining its end use function to a greater degree than its chemical composition does” [e.g. a chair or computer]
- “*Polymer* means a substance consisting of molecules characterised by the sequence of one or more types of monomer units…” [e.g. a plastic]
- “*Intermediate* means a substance that is solely manufactured for and consumed in or used for chemical processing in order to be transformed into another substance…
 - (a) *non-isolated intermediate* means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. ...
 - (b) *on-site isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one more legal entities;
 - (c) *transported isolated intermediate* means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;”

- “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, or the countries acceding to the European Union on 1 May 2004, 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, or in the countries acceding to the European Union on 1 May 2004, but not placed on the market by the manufacturer or importer;
- (c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 May 2004, and between 18 September 1981 and 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.”

- “Importer means any natural or legal person established within the Community who is responsible for import”
- *Note that many of the registration requirements in REACH are based on the tonnes per annum (tpa) of the substance manufactured or imported **by the company concerned**, not the total amount produced or imported.*

Most of these definitions are very similar to those already in use in the existing European chemicals legislation, though some are new – e.g. *phase-in substance*.

3. Substances totally exempted from REACH

The following groups of substances are totally exempt from REACH:

- radioactive substances within the scope of Council Directive 96/29/Euratom
- substances, on their own, in a preparation or in an article, which are subject to customs supervision, provided that they do not undergo any treatment or processing, and which are in temporary storage, or in a free zone or free warehouse with a view to re-exportation, or in transit;
- non-isolated intermediates.

4. Registration

Registration is the main procedure for collecting safety information into the Agency’s databases.

Article 5 lays out the basic requirement of registration:

“Save where this Regulation provides otherwise, any manufacturer of a substance in quantities of 1 tonne or more per year shall submit a registration to the Agency.

Save where this Regulation provides otherwise, any importer of a substance, either on its own or in a preparation, in quantities of 1 tonne or more per year shall submit a registration to the Agency.”

It is important to note that this requirement to register applies to substances produced in Europe, substances imported into Europe, and substances imported into Europe in preparations (mixtures of chemicals).

The 1 tonne total refers to the total amount manufactured and imported – i.e. if a chemical is imported in several preparations by one company, REACH will use the total tonnage of the substance imported by the company.

4.1 Exemptions from registration

The key step that determines the scope of REACH is the registration procedure (Title II).

There are three main levels of exemption from registration, firstly a series of cases in which substances are exempted from registration if they

have specific uses, the second a list of fully exempt substances and the third being a list of substances that are subject to more limited registration requirements:

Article 4 provides that the registration requirements shall not apply to the extent that a substance is used:

- in medicinal products for human or veterinary use within the scope of Regulation (EEC) No 2309/93, Directive 2001/82/EC of the European Parliament and of the Council and Directive 2001/83/EC of the European Parliament and of the Council
- as a food additive in foodstuffs within the scope of Council Directive 89/107/EEC
- as a flavouring in foodstuffs within the scope of Commission Decision 1999/217/EC
- as an additive in feeding stuffs within the scope of Council Directive 70/524/EEC
- in animal nutrition within the scope of Council Directive 82/471/EEC”

A limited list of substances are fully exempt from registration:

- Those listed in annex II – these tend to be food-related chemicals, such as glucose, and also other chemicals considered safe such as water.
- Those listed in annex III – assorted exemptions including chemicals created by chemical reactions within products, crude oil, natural gas and “Minerals, ores, or substances occurring in nature if they are not chemically modified during their manufacturing, unless they meet the criteria for classification as dangerous according to Directive 67/548;” – this would be expected to include, for example, common salt.
- Polymers, with one important exception:
 - Manufacturers and importers of polymers must register any non-registered monomers within those polymers if they make up more than 2% of the weight of the polymer, and are produced or imported at 1 tpa or more.

Substances subject to more limited registration:

- **Chemicals already notified under the current new chemicals system (1981) will be considered registered under REACH.**
- **Substances being used for product and process oriented research (PPORD) and development** (e.g. a chemical being used in the development of a new product) can be exempted from registration for 5 years, extendable by a further 5 (or 10 if used in medicinal products). Companies will need to submit a short notification to the agency, who will decide whether to accept the exemption.
- **Substances used in plant protection or biocidal products will be considered registered for those uses through the relevant vertical legislation.**
- **On-site isolated intermediates and transported isolated intermediates have a more limited registration**, based on existing information, except in the case of transported isolated intermediates manufactured or imported at 1000 tpa or more, when the registration must include ‘annex V’ information – i.e. the same information as a 1-10 tpa marketed chemical.

Substances in articles:

- **If an unregistered substance is present in articles e.g. imported chairs, the draft regulation makes distinctions between two situations:**
 - If it is intended to be released, is present in the articles at 1 tpa or more, and is classifiable as dangerous, then it should be registered.
 - If it is found that it is likely to be released (but no investigation of this possibility is required in advance), is present in the articles at 1 tpa or more, is classifiable as dangerous and the quantity released may adversely affect human health and the environment, then the Agency must be notified (with a simple set of information), and they may then decide to ask for a full registration. An example of this is if an NGO finds there is a release, they would then tell the manufacturer who then would be obliged to assess if it meets the other criteria.

- **NB: This provision does not come into force until 3 months after the final registration date for phase in substances, i.e. around 2018, when all existing chemicals will have been registered. Prior to this point there is no registration obligation of any sort on an importer of articles.**

4.2 Registration requirements vary by tonnage

The registration requirements vary by tonnage produced or imported per producer/importer – they are prioritised so that higher volume chemicals require more safety information, as shown in Table 1. This table also includes an estimate of how many phase-in chemicals fit into each category, from a report from the Commission’s Joint Research Centre [4].

It is important to note that a chemical produced at 100 tpa and above is registered with only available data and a *testing proposal* for new data for

annexes VII & VIII. The new safety information requested in these annexes does not need to be available at this point, and the need or otherwise for this information will be established in Dossier evaluation of the testing proposal.

REACH does not require new test data; if existing studies are available they can be used, wherever in the world they are generated. REACH demands information on the safety of substances – but industry is able to provide this information through old tests, comparisons with other similar substances etc, as long as they can justify this. Industry is also able to argue that some safety information is unnecessary, for example because of the exposure pattern of the chemical. Annex IV outlines the whole process, Annexes V-VIII outline information requirements for different tonnages, and Annex IX has the guidelines for adaptation (reducing) the information requirements.

Annex 1 explains how industry should take the safety information they have gathered, and relate

Table 1: Registration requirements in the REACH system, and estimated number of substances [4]

1-10 tpa	Generally in vitro safety information (described in Annex V) (no chemical safety report) [17,500 substances], plus all available data
10-100 tpa	Chemical Safety Report (analysis of hazards, exposures and safe uses) and the safety information listed in Annex V + VI [4977 substances]
100-1000 tpa	Chemical Safety Report, Annex V+VI, existing information they have for Annex VII and a testing proposal for the provision of new information in Annex VII . [2641 substances] This testing proposal will be reviewed by the authorities in a dossier evaluation , and can include e.g. justifications as to why testing is not needed.
1000 tpa and above	Chemical Safety Report, Annex V+VI, existing information they have for Annex VII and VIII and a testing proposal for the provision of new information in Annex VII and VIII . [2704 substances] This testing proposal will be reviewed by the authorities in a dossier evaluation , and can include e.g. justifications as to why testing is not needed.
On site isolated intermediate at 1 tpa and above	Available data
Transported isolated intermediate at 1 tpa and above	Available data, and if produced at 1000 tpa and above, annex V (as in 1-10 tpa registration of traded chemical) . [1,700 substances at 1000 tpa and above]

to their knowledge about the uses of the chemical (expressed as exposure scenarios), in order to create a chemical safety report. Only if a substance “meets the criteria for classification as dangerous according to Directive 67/548/EEC or Directive 1999/45/EC or is assessed to be a PBT or vPvB” does the registrant have to assess exposure and do a risk assessment (see [5] for an amended version of Directive 67/548/EEC for these definitions). In these cases, the chemical safety report must include a description of risk management measures that should be taken to ensure that the risks in each exposure scenario are adequately controlled. If a chemical is not classified as dangerous, the exposure and risk assessments are not required.

For chemicals produced at below 10 tonnes per annum a chemical safety report is not required, so the producer will not be obliged to establish what risk reduction measures are needed for safe use. However, the Commission would argue that in order to comply with the general requirement to recommend risk management measures in safety data sheets, some sort of risk assessment will be required.

It is also worth noting that the registration dossiers will be submitted to the agency who will only do a basic completeness check – there will be no detailed analysis of the information in the dossiers unless the dossier is selected for evaluation. It is only in evaluation that any industry data and justifications will be examined by the regulator.

4.3 Timetable for registration

Chemicals that are new to the European market will continue to be subject to pre-market registration, as in the current system (in place since 1981), however the registration threshold has

been increased from 10 kg/year to 1 tonne/year. In addition, in the current system a notifier must wait 60 days before putting a new substance on the market, whilst in REACH they only need to wait 21 days.

A major challenge for REACH is the phasing in of registrations for the backlog of existing chemicals, which have so far escaped effective regulatory scrutiny. This ‘burden of the past’ is estimated to be around 30,000 chemicals, all of which have been on the EU market since before 1981. The registration of these “phase in” chemicals will be gradual, with 3 deadlines, prioritised on the basis of tonnage produced and with accelerated registration for carcinogens, mutagens and reproductive toxins – see Table 2.

It is important to note that in order to qualify for this phase in period a registrant must pre-register with some basic information by a deadline of Entry into Force (EOF) +18 months for substances in the 1000 tpa or above band, and by EOF+4.5 years for all other substances. One aim of this pre-registration is to assist in consortium formation and data sharing.

4.4 Data sharing and consortia

REACH contains extensive mechanisms to encourage and frequently force companies to share safety data on their chemical; in the case of information from animal tests it is mandatory that it is shared. This means that in many cases companies will share the work in producing a registration dossier, often through forming a consortium. It is important, however, to distinguish between the mandatory Substance Information Exchange Forum used for data sharing, and the voluntary consortia, used for Registration.

Table 2: Phase in dates for registration of existing chemicals

3 years after the entry into force (EOF) of REACH	Those chemicals produced and imported at 1000 tpa or more, and those chemicals produced or imported at 1 tpa or more and which are classified as CMR category 1 and 2.
6 years after EOF	those chemicals produced and imported at 100-1000 tpa.
11 years after EOF (2018 assuming 2007 EOF):	those chemicals produced and imported at 1-100 tpa.

In addition, a company producing a low volume of a chemical will often find that it has already been registered by higher volume producers by the time the low volume deadline has been reached.

REACH provides a number of mechanisms to allow a later registrant to use data from earlier registrations.

The UK Government has been proposing a strengthening of the pressure for industry to co-operate in registering chemicals through a proposal for only one substance one registration (OSOR) – this proposal is currently under development and discussion in Council.

5. Evaluation

The dossiers collected in the registration process will only be checked by the Agency for completeness; their accuracy will not be checked at all unless they enter the ‘evaluation’ stage.

NB: On-site isolated intermediates are exempt from normal evaluation but can be subject to checking by the relevant national authority.

Evaluation is carried out by Member State authorities, co-ordinated by the Agency, but all decisions (e.g. requests for more safety data) must be approved through a European process, in which all Member States must agree with the proposal, or if unanimity can’t be reached, the Commission takes the decision. This makes it impossible for any Member State to operate in isolation.

There are three forms of evaluation:

- **Dossier evaluation (testing proposals) – this is compulsory for all 100 tpa and over chemicals**, and involves an examination of the testing proposals for the provision of information in Annexes VII and VIII.
- **Dossier evaluation (compliance check) – this is voluntary for member state authorities**, and involves checking the accuracy of the registration dossier, and whether it fulfils the legal requirements.
- **Substance evaluation – The agency and member states will create a rolling plan of substances to be evaluated in more depth, with prioritisation so that the worst chemicals are examined first.** In some cases such an evaluation will lead to further action, for example authorisation or restrictions.

6. Authorisation

Authorisation is a procedure for **controlling the use of chemicals of very high concern**. The **chemicals of very high concern**, are defined as follows:

- Category 1 & 2 Carcinogens, Mutagens and Reproductive toxins
- Chemicals that are persistent, bioaccumulative and toxic (PBT), based on scientific criteria.
- Chemicals that are very Persistent and very Bioaccumulative (vPvB), based on scientific criteria.
- Chemicals that are “identified as causing serious and irreversible effects to humans or the environment which are equivalent [to the other chemicals above]”.
- The biggest difference between authorisation and restrictions is that **in authorisation all uses of a chemical are banned except those that industry comes forward to defend**, whilst **in restrictions authorities provide the justifications for banning specific uses** (or in some cases production).
 - Therefore, in restrictions, the regulator must find out which uses exist, and which should be restricted, whilst considering whether safer alternatives are available in the case of important uses. In authorisation, it is industry that states which uses it wants to continue, and it has to make a case for those uses continuing. Authorisation also encourages producers of alternative substances to bring forward information, and in some circumstances will force the applicant to prepare a substitution plan.

6.1 Authorisation process

Not all chemicals of very high concern will enter authorisation immediately, as there will first be a prioritisation process involving the Agency to identify those chemicals of most concern. Once chemicals have been selected through this prioritisation process (with a consultation), they will then enter the full authorisation process. It has been suggested that in the first years of operation of REACH the

authorisation process will only process tens of chemicals per year, but numbers will increase as the REACH procedures become more established.

A deadline will be set when use of the chemical must cease, except when industry has successfully applied to continue use, either because they argue that the chemicals will be used under ‘adequate control’ (Article 57.2) or that socioeconomic factors and lack of safer alternatives means that use should continue, despite a lack of ‘adequate control’ (Article 57.3).

6.2 Exemptions from the authorisation system

Exemptions from the authorisation system are the same as those from registration (above), but also include:

- Uses as plant protection products or as biocides.
- Uses as on-site isolated intermediate or transported isolated intermediate.
- Uses in scientific research or PPORD.
- If the authorisation relates to a human health problem, then uses in cosmetics or food contact materials are exempt, based on the assumption that the specific vertical pieces of legislation should cover human health concerns.
- Substances present at low concentrations in preparations.

7. Restrictions process

The restrictions process is the ‘safety net’ to deal with “*unacceptable risks to human health and the environment*”, through adopting restrictions on manufacture, use and/or placing on the market of a substance. The REACH restrictions process is similar to the current marketing and use regulations.

Chemicals do not have to be registered in order to be restricted. The restrictions process can deal with chemicals that are exempt from the registration process, and can also lead to action being taken on a ‘phase in’ chemical that has not yet been registered.

The core of the restrictions process is the preparation, by the Agency or Member States, of a

dossier which demonstrates that a risk to human health or the environment is not adequately controlled. This dossier is then discussed within the Agency’s committees, with decisions eventually being taken by the Commission through a Comitology procedure (a commonly used EU decision making procedure involving Member State experts).

Because of the ‘safety net’ nature of the restrictions process, there are few exemptions, basically just those concerning waste, and human health risks from cosmetics (to be dealt with by the cosmetics directive).

8. The Agency

REACH sets up a new European Chemicals Agency to administer the REACH regulatory system. It has already been decided by Council that this Agency will be based in Helsinki. As explained in the REACH explanatory memorandum [1]:

“The Agency manages the registration process, plays a key role in ensuring consistency of evaluation, provides criteria to guide Member States’ selection of substances for evaluation and takes decisions requiring further information on substances under evaluation. It also provides opinions and recommendations in the authorisation and restriction procedures and has duties with regard to confidentiality”

The Agency will have a Management Board, and a number of committees, including a committee on risk assessment and one on socioeconomic assessment (for establishing recommendations in the authorisation and restrictions procedures), a Member State committee (for decision-making involving the Member States), a forum for exchanging information on enforcement (with Member State representatives), and a Board of Appeal.

It is legally impossible for the Agency to enforce REACH, due to restrictions in the EU treaty (and Constitution) – enforcement must happen at Member State level.

9. Classification and labeling

Companies who market substances and preparations must currently classify and label their products. Under REACH this Classification and

Labelling information will be entered into an inventory, which will be published on the Agency's web site. Substances covered by the inventory will be as follows:

- All substances that have been registered in the first 3 years of REACH, with the information taken by the Agency from the registration dossier.
- Within 3 years of REACH coming into force, industry self-classifications of any substances which are *placed on the market*, and are either:
 - Subject to registration >3 years after REACH comes into force, or;
 - Meet the criteria for a dangerous substance or preparation.

If classifications differ for the same substance, the registrants and notifiers should “make every effort” to agree a joint classification; if they fail the database will list all the classifications submitted for that substance.

Under the current system, regulators can harmonise classification and labelling of substances. Under REACH, this harmonisation is restricted to CMR properties and respiratory sensitisers – all other harmonisation will be the responsibility of industry.

10. Information flow and access to information

REACH will generate a lot of information – however, this information will not all be publicly available, with some information only being accessible to regulators. As far as public access is concerned, information held by the Agency is divided into three categories:

- A “White list” of information that will always be publicly available, and which will be accessible on the REACH internet database, including the bulk of the information on the safety data sheet.
- A “Black list” of information that will never be made available, for example precise production tonnages.
- A “Grey list” of information which will only be available on application, after consulting

the provider of the information to find it if it can be disclosed.

11. References

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