



March 2007

REACH AT A GLANCE

1. Where does REACH come from?

In April 1998, the failure of the existing substances regulation led the European Environment Council to launch the chemicals policy review.

The Council called on the Commission to “develop a new, integrated and coherent chemicals policy adequately reflecting the precautionary principle and the principle of sustainability and specifying the obligations incumbent on the parties involved”.

The main objectives of this review were to:

- Deal with the “burden of the past”
- Shift responsibility from authorities to industry, including downstream users
- Enhance innovation
- Substitute dangerous chemicals
- Integrate the precautionary principle
- Facilitate risk management decisions.

As a result, on 29 October 2003 the European Commission issued a proposal for a new chemicals regulation, called "REACH". REACH stands for **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals.

After more than three years of heated debate, REACH was adopted at the end of 2006:

- MEPs voted REACH on Wednesday 13 December 2006
- Council endorsed the regulation on Monday 18 December 2006
- REACH was published in the EU Official Journal on 30 December 2006
- REACH will enter into force on 1 June 2007

The REACH regulation will replace most of the EU chemicals legislation in place and will set up a European Chemicals Agency in Helsinki.

2. What does REACH mean for industry?

The main challenges for the industry will be to:

- assess substances (including data generation)



- document the use of these substances (Chemical Safety Report)
- register these substances with the Chemicals Agency (together with other manufacturers/importers and possibly downstream users)
- communicate good practice (via Safety Data Sheet)
- substitute substances of high concern

These tasks will have to be carried out for 30,000 substances in 11 years.

3. The main steps in REACH:

REACH sets up a single system for new and existing substances. The main steps in REACH are:

- Pre-registration: facilitating data sharing and avoiding unnecessary testing
- Registration of substances of 1 tonne or more per manufacturer or importer per year
- Information in the supply chain, involving downstream users
- Evaluation of dossiers and substances by the Agency and Member States
- Authorisation for substances of very high concern
- Restrictions of substances to certain uses

3.1. Scope of REACH:

REACH covers:

- manufacturing, importing, placing on the market and use of substances
- substances “on their own”, in preparations or in articles

General exemptions from the scope of REACH:

Radioactive substances, substances under customs supervision, the transport of substances and non-isolated intermediates are not covered under REACH. Waste is also specifically exempted. A number of other substances are exempted from parts of the provisions of REACH, where other equivalent legislation applies (for example substances used in medicinal products).

3.2. Pre-registration

Manufacturers and importers must pre-register substances that are already on the EU market, if they want to benefit from transitional arrangements that allow them to be registered at a later stage (over 11 years according to tonnage band - see timetable at end of document).

Pre-registration also enables registrants to share data with other registrants and avoid carrying out redundant tests. Pre-registration is limited to the period from 1 June 2008 to 1 December 2008.



The following information is required for pre-registration:

- Name and address of the producer (or third party)
- Substance name plus EINECs and CAS n° (if available)
- Substance name (as previously) for where either (Q)SARs are available or read-across is applicable.
- The envisaged deadline for the registration/tonnage band

3.3. Registration

Each manufacturer and importer of chemical substances (≥ 1 tonne/year) must submit a registration dossier documenting the physicochemical, health and environmental properties of their substances and assessments to the Agency.

What has to be registered?

- Substances >1 tonne/producer or importer/year
- Substances in articles if present > 1 tonne, AND dangerous (67/548/EEC) AND intended for release

Exemptions from Registration (Annexes IV and V):

- 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

3.4. Information requirements

To register, manufacturers and importers of substances will need to gather information on the environmental and health properties of their substances, assess the risks arising from the uses of their substances and ensure that these risks are properly managed. To demonstrate that this has been done, manufacturers and importers need to submit:

- a technical dossier, for substances in quantities of 1 tonne or more per year, and, in addition,
- a chemical safety report, for substances in quantities of 10 tonnes or more per year.

What should be included in the Technical Dossier for Registration?

- 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)

What is the Chemical Safety Report?

The Chemical Safety Report shall consider all stages of the life-cycle of a substance as defined by the identified uses and provide the following assessments:

- Human health hazard assessment of physicochemical properties
- Environmental hazard assessment
- PBT and vPvB assessment
- Exposure assessment
- Risk characterisation

3.5. Data sharing

Potential registrants have to take part in the data sharing mechanisms through a SIEF (Substance Information Exchange Forum). The aim is to exchange information to minimise duplication of tests.

SIEF participants provide others with existing studies, react to requests by others, identify needs for further studies and arrange to carry them out.

- To limit vertebrate animal testing as far as possible, the sharing of tests involving vertebrate animals is mandatory. If participants refuse to share this information it would lead to sanctions.
- Sharing of tests involving non-vertebrate animals and physicochemical data is obligatory if any of the other potential registrant requires this information.
- The rest of SIEF proceeds without fulfilling mandatory requirement.

3.6. Communication in the supply chain – Involvement of downstream users

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. The



quality of the SDSs is expected to improve due to REACH as more information will be available as a result of the registration process.

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.

3.7. Evaluation

The Agency will perform dossier evaluation. The Agency will also coordinate substance evaluation, which will be conducted by the Member States to investigate chemicals of concern.

What will they evaluate?

- Dossier evaluation by the Agency:



- Examination of testing proposals: to prevent unnecessary animal testing, i.e. the repetition of existing tests, as well as poor quality tests
- Compliance Check: the Agency may check the compliance of registration dossiers to check if they comply with the registration requirements. At least 5% of dossiers should be checked;
- Substance evaluation by Member States
 - Examination of substances that could present a risk and recommendation for further tests if needed

3.8. Authorisation process

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.

How will substances of very high concern be regulated?

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.

3.9. Restrictions

REACH foresees a restriction process to regulate the manufacture, placing on the market or use of certain substances within the EU territory if they pose an unacceptable risk to health or the environment. Such activities may be limited or even banned, if necessary. The restriction is designed as a “safety net” to manage risks that are not addressed by the other REACH processes.

Any substance on its own, in a preparation or in an article may be subject to restrictions if it is demonstrated that risks need to be addressed on a Community-wide basis.

Restrictions of a substance can apply to all uses or to specific uses.

All uses of a restricted substance which are not specifically restricted are allowed under REACH unless they are subject to authorisation, or other Community or national legislation regulating their use.

There is no tonnage threshold for a substance to be subject to restriction.

Proposals for restrictions will be prepared by Member States or by the Agency on request of the Commission in the form of an Annex XV dossier.

The Annex XV dossier should demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and should identify the most appropriate set of risk reduction measures.

Interested parties will have an opportunity to comment and the Agency will provide opinions on any proposed restriction.

Deadlines for the decision-making process have been included in REACH in order to speed up the restriction procedure.

Annex XVII of the REACH Regulation contains the list of all restricted substances, specifying which uses are restricted. The existing restrictions set out in the Marketing and Use Directive (76/769/EEC), e.g. the ban on asbestos and restrictions on the uses of certain azo-dyes, were carried over to REACH.

3.10. 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.

3.11. Enforcement

Enforcement of REACH towards companies is a task for the Member States.

They shall maintain a system of official controls and inspections and set effective, proportionate and dissuasive penalties in national legislation.

In order to coordinate the enforcement of REACH, a Forum for Exchange of Information (“Forum”) will be established within the Agency.

Main dates for pre-registration and registration	
Article 28 – pre-registration of existing substances of 1 tonne+ per year.	1 June 2008 until 1 December 2008.
Article 23(1) – registration provisions for existing substances for CMR (cat 1 or 2) and toxic (R50/53) over 1 tonne + per year, and other substances over 1,000 tonnes per year.	1 December 2010.
Article 23(2) – registration provisions for existing substances of 100 tonnes or more per year.	1 June 2013.
Article 23(3) - registration provisions for existing substances of 1 tonne or more per year.	1 June 2018.