



REACH me: Where we are today

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REACH, the new European Regulation, seeks to make the manufacturers and importers who place chemicals on the market responsible for understanding and managing the risks associated with their use. REACH is aimed at simplifying the control of chemicals in the European marketplace. It replaces a patchwork of European Directives with a single system.

Different types of chemicals are considered in different ways by the legislation, and some are exempt, because specific laws already cover them. Enforcing this very wide-ranging new system presents new challenges to regulators across Europe and to the international trade.

REACH places new duties on a range of different businesses, especially to manufacturers and importers of chemicals, but also to downstream users of chemicals and to article producers. At present, numerous questions are still unresolved and useful tools are missing or not yet ready.

Status today

On 27 February 2001, the European Commission issued a White Paper on a Strategy for a future Chemicals Policy. This has subsequently been developed and extensively discussed with major stakeholders, resulting in the release on 29 October 2003 of the Commission's proposal called REACH. It deals with the Registration, Evaluation, Authorisation and Restriction of Chemical substances and their safe use.

The European Parliament's first reading of the REACH proposal was finalised on the 17th of November 2005, and the Council reached a political agreement on the 13th of December 2005. The resulting new European Community Regulation was formally adopted on 18 December 2006 by the Council of Ministers following the vote in second reading of the European Parliament on 13 December 2006.

REACH entered into force on 1 June 2007. The provisions under REACH on pre-registration and registration, evaluation, authorisation and downstream user obligations apply as from the 1 June 2008. REACH replaces about 40 pieces of legislation related to chemicals and is complementary to other environmental and safety legislation. It will not replace sector specific legislation (for example on cosmetics or detergents).

REACH makes industry bear most responsibilities to manage the risks posed by chemicals and provide appropriate safety information to their users. Companies are involved if they have any kind of business relating to chemical or to chemical releasing articles in any of the 27 European Union (EU) Member States: Austria, Belgium, Bulgaria, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Latvia, Lithuania, Luxembourg, Netherlands, Malta, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden and United Kingdom. In addition, the European Economic Area with Iceland, Liechtenstein and Norway are planning to

transpose REACH to their national legislation. When this has taken place the same requirements will apply to these countries.

ECHA, The EU Co-ordinator

The European Chemicals Agency (ECHA) located in Helsinki, Finland, will manage the paperwork and processes for chemical substances to ensure consistency across the EU. Today ECHA is building up its organisation and recruiting personnel to be ready to accept registrations from 1 June 2008.

Its main tasks are to manage the registration process and carry out dossier evaluations. It will also co-ordinate the substance evaluation process and will take most of the decisions resulting from those evaluations. Where appropriate, authorities may also select substances for a broader substance evaluation to further investigate substances of concern.

Nevertheless, REACH gives greater responsibility to industry to manage the risks from chemicals, and to provide users in the supply chain with safety information on the substances. All manufacturers and importers of chemicals must identify and manage risks linked to the substances they manufacture and market.

Registration obligations and how to fulfil them are explained in detail in the REACH guidance documents called REACH Implementation Projects (RIP). They can be found on the website of the ECHA or of the European Chemicals Bureau (ECB), whose main task in the interim period is to develop a Technical Guidance Document (TGD) and Informations Technology (IT). These are the tools that will enable the industry and authorities to administer the legislation effectively from the start. However, by the third quarter 2007, most of these documents and tools are not yet available, but are still in preparation.

The following RIPs (Reach Implementation Projects) have been finalised:

- RIP 3.1: Guidance on Registration
- RIP 3.2-1A: TGD (Technical Guidance Document) on preparing the Chemical Safety Report (CSR) Scooping
- RIP 3.2-1B: TGD on preparing the CSR Draft: Chemical Safety Assessment (CSA)
- RIP 3.3-1: TGD on information requirements (Scooping)
- RIP 3.3-2: TGD on information requirements
- RIP 3.4: TGD on data sharing
- RIP 3.5-1: TGD on Downstream User requirements, preliminary study
- RIP 3.8: Guidance on fulfilling the requirements for articles
- RIP 3.9-1: Preliminary study on Socio-Economic Analysis
- RIP 3.10: TGD on Identification and Naming of Substances in REACH
- RIP 4.1/4.2 Guidance on Dossier/Substance evaluation
- RIP 4.4: TGD on the preparation of Annex XV dossiers

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The projects that are currently running:

- RIP 2: REACH IT
- RIP 3.2-2: TGD on preparing the CSR (Chemicals Safety Report)
- RIP 3.5-2: TGD on Downstream User requirements
- RIP 3.6: Guidance on Classification and Labelling under Global Harmonised System (GHS)
- RIP 3.7: Guidance on preparing an application for authorisation
- RIP 3.9-2: Guidance on carrying out a Socio-Economic Analysis
- RIP 4.3/4.5: Guidance document on inclusion of substances in annex XIV and guidance document on priority setting for evaluation

REACH Exemptions

Generally, REACH applies to all individual chemical substances, both on their own and in preparations, or in articles if the substance is intended to be released during normal and reasonably foreseeable conditions of use.

Some substances are specifically excluded:

- Radioactive substances
- Substances under customs supervision
- The transport of substances
- Non-isolated intermediates
- Waste
- Some naturally occurring low-hazard substances

In addition, some substances covered by more specific legislation, having tailored provisions, including:

- Human and veterinary medicines
- Food and foodstuff additives
- Plant protection products and biocides

Other substances have tailored provisions within the REACH legislation, as long they are used in specified conditions including:

- Isolated intermediates
- Substances used for research and development
- Polymers

Actors involved in the REACH process

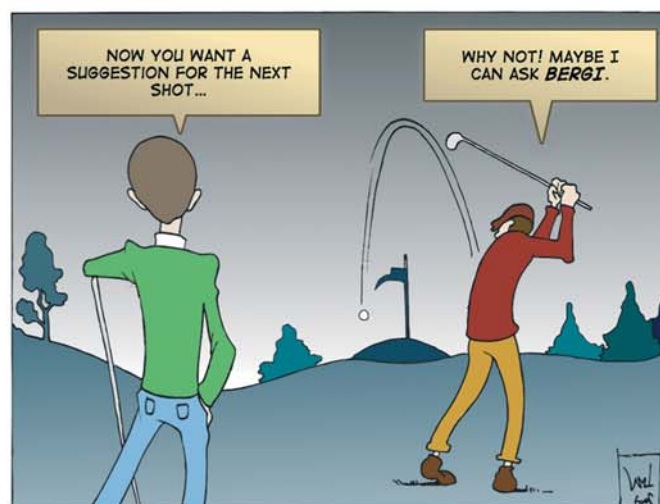
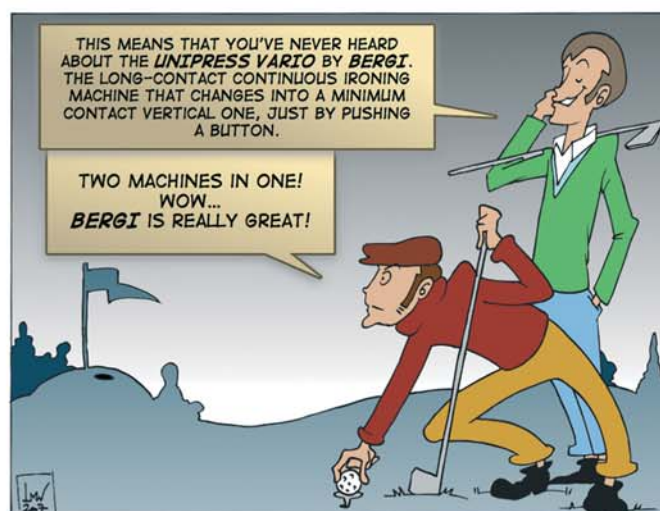
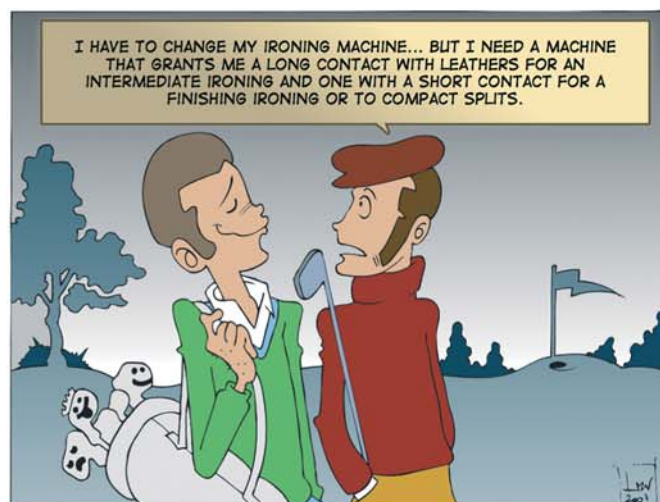
There are three main types of actors involved in the REACH processes:

- The authorities with ECHA as co-ordinator
- The industry
- Some third parties

Industry actors are of special importance, as they have to perform different obligations; basically they bear the brunt including the cost. REACH Regulation determines that by 1 June 2008 the Commission must issue a Regulation describing the fees that the chemical manufacturers and importers will have to pay to register their chemicals. These fees are supposed to pay for 80% of the budget of the ECHA.

The following industry types can be distinguished:

MANUFACTURER/IMPORTER: The organisation manufactures or imports a substance on its own or in a preparation of ≤ 1 ton/year. ➤

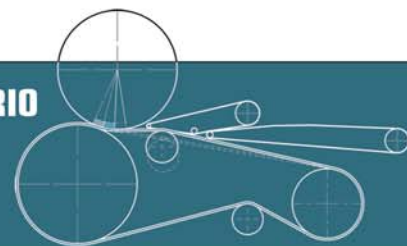


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PRODUCER/IMPORTER OR SUPPLIER OF ARTICLES: The organisation manufactures/imports articles which release chemicals or places them on the market.

DISTRIBUTOR (INCLUDING RETAILERS): The organisation stores and places on the market a substance, on its own or in a preparation.

DOWNSTREAM USER: The user uses a substance, either on its own or in a preparation, in the course of industrial or professional activities, for example: formulation, dilution, repackaging, spraying or painting.

Obligations

The manufacture or importer of one ton or more of any chemical substance per year, should pre-register the substance with the ECHA between 1 June and before 1 December 2008. Failure to meet this deadline means that one cannot continue producing or importing the substance until a full registration dossier has been submitted. However, if one has pre-registered one can benefit from staggered registration deadlines depending on the substance and the tonnage (2010, 2013 or 2018).

The REACH Regulation also applies in certain cases to articles. These include in principle leather and textiles as shoes and clothes. Substances contained in the articles are to be registered if they are intended to be released. This is unlikely to be the case for these items.

If the articles contain substances of very high concern which are listed on the "candidate list", the importer and all distributors of the article have the obligation to notify these substances to the Agency if the substance is present in those articles in quantities over 1 ton per producer/importer per year, and the concentration is above 0.1% (weight/weight). On request, the importer also has the duty to communicate information on substances of very high concern in articles to users and consumers, enabling them to use the substance safely.

Any manufacturer or importer can appoint a third party representative located in the EU to fulfil the obligations related to pre-registration in order to protect confidential business information. This is important if a non-EU company does not wish the importer to be responsible for the registration because they do not wish to disclose confidential information. In this case, the third party called "the only representative" takes over all obligations of the importers under REACH.

For pre-registration, the potential registrant needs to submit to the Agency only basic information on the produced or imported substance. At the present time neither suitable tools nor appropriate instructions are available to start this work. Nevertheless, it is recommended to create an inventory of all substances or substances in preparations and articles that are subject to import, distribution or handling within the EU. The Council's common position requires the following information for pre-registration:

- Name of the substance
- Name(s) in the IUPAC (International Union for Pure Applied Chemistry) nomenclature or other international chemical name(s)
- Other names as usual name, trade name, abbreviation
- EINECS (European Inventory of Existing Commercial Chemical Substances Information System) or ELINCS (European List of Notified Chemical Substances) number if available and appropriate
- CAS (Chemical Abstract Service) name and CAS number if available

- Other identity code (if available)
- Name and address of the potential registrant
- Name of the contact person
- Name and address of the representative where appropriate
- The envisaged deadline for the registration/tonnage band
- Indicate the substance(s) which one intends to use for read-across approach or quantitative structure-activity relationship

Pre-registration applies to the so called "phase-in substances". These are substances listed in the EINECS, or those that have been manufactured in the Community, but not placed on the Community market, in the last 15 years or the "no longer polymers" of Directive 67/548.

The passage of information up and down the supply chain is a key feature of REACH. This refers for example, to the exchange of information on use and exposure between downstream users and manufacturer or importer. Users should be able to understand what manufacturers and importers know about the dangers involved in using chemicals and how to control risks. REACH requires downstream users to identify and apply appropriate measures to adequately control the risk identified in any safety data sheet supplied to them. Distributor and Retailers must sustain the information flow within the supply chain.

IT tools and Helpdesk

Without an appropriate IT tool, it would be extremely difficult for industry—especially for small and medium enterprises—to comply with the REACH data requirements. To support companies in registering substances, the Agency and Member States in evaluating dossiers, and to help the public in accessing information on chemicals, the industry has to use IUCLID 5, the International Uniform Chemical Information Database, to submit the registration dossiers. IUCLID 5 is a software application to capture, manage and exchange data on properties of chemicals. The software can be downloaded on the web pages of the ECB and can be used free of charge.

It is critical for this project for the pre-registration process to be operational by 1 June 2008. However, this part of IUCLID 5 is still missing.

Also, the REACH-IT software isn't ready, which provides an online homepage to submit registration dossiers on chemicals. It also allows the Agency and Member States authorities to review the dossiers. The Agency will make non-confidential information accessible on this website.

Further the Industry will be responsible to manage and operate the Substance Information Exchange Forum (SIEF) which is the mandatory forum to share information. In order to make the SIEFs workable, clear processes and IT support are needed. One of the objectives of SIEF is to limit vertebrate animal testing as far as possible, while balancing that with the generation of necessary information to identify the hazard of substances.

National REACH helpdesks provide wide ranging information on the provisions of REACH. They will also advice on the responsibilities to fulfil the Regulation. They will not, however, focus on providing tailor-made information on how those obligations should be met, and information is often of varying quality. The ECHA helpdesk is to answer questions regarding REACH provisions on administration of dossiers or transmission of dossiers and related issues.

In addition, those who are not familiar with REACH can find their obligations using the electronic Navigator tool. It applies to specific substances. The Navigator will provide a list

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of obligations for a given substance, based on the answers the user gives to a series of questions. The Navigator can also be found on the ECHA, or on the ECB (European Chemicals Bureau), web pages.

Commission review of Annex I, IV, V, XI and XIII

Within the first 18 months after the entry into force of REACH, the Commission has been tasked to carry out a number of reviews of the following Annexes of the Regulation:

- Annex I—General provision for assessing substances and preparing Chemical Safety Reports
- Annex IV—Substances exempted from registration where sufficient information is known and the risk is minimal
- Annex V—Substances exempted from registration under the current legislation
- Annex XI—General rules for adaptation of the standard testing regime set out in Annexes VII to X
- Annex XIII—Criteria for the identification of PBTs (Persistent, Bio-accumulative and Toxic) and vPvBs (very Persistent, very Bio-accumulative)

The Commission will involve Member States and other stakeholders on the reviews in a sub-group of the REACH Competent Authorities.

In particular, Annex IV should not be overlooked since it gains importance. Annex IV contains a list of substances that are exempted from the registration, evaluation and downstream user provisions of REACH. This is because sufficient information is known about the substances and their intrinsic properties, that they are considered to involve minimum risk. These substances will be reviewed and criteria will be established for exemptions.

REACH will ban some chemicals. Existing restrictions on marketing and use of chemicals will remain in place and be transferred to REACH. Further substances may be included on a candidate list of 'substances of very high concern' from autumn 2008 and made available on the ECHA website.

Recommended REACH preparations

- Recognise within your company who will be responsible for REACH compliance.
- Check if the substances or uses in your inventory are exempted from one or all aspects of REACH.
- For each substance, identify which role your company needs to act under REACH.
- Make preparation by establishing a dialogue through the supply chain on uses and use conditions according to the role as Manufacturer or Importer, Producer or Importer or Supplier, Distributor (including Retailers) or Downstream user.
- Create an inventory of all substances or substances in preparations/articles that you import/distribute/handle or use.
- Identify and plan for future responsibilities, which are crucial for continuity of the business.
- For any questions or uncertain use the national or ECHA Helpdesk
- Ask your national industry organisations for support.
- Check for update and new information—mainly the ECHA and other relevant web pages.

Additional Information

ECHA Home page: http://ec.europa.eu/echa/home_en.html

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