

The European REACH Directive in a Nutshell

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Public

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Exactly your chemistry.



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REACH in a nutshell

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Exactly your chemistry.

Clariant Group overview

- Clariant is a global leader in the field of specialty chemicals
- It has some 23 000 employees and posted annual sales of about CHF 8.2 billion for 2005
- The group operates worldwide with more than 100 companies on five continents
- It is domiciled and headquartered in Muttenz near Basel/Switzerland
- The products and services of its five divisions are based on innovative specialty chemicals
- These products and services play a decisive role in our customers' manufacturing processes and upgrade their finished products

Preparing for REACH
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*REACH is the acronym for **R**egistration, **E**valuation and **A**uthorization of **C**hemicals*

■ Registration:

- For all substances produced or imported in quantities of 1 ton or more per year, manufacturers and importers must prepare a registration dossier to be submitted to the European Chemicals Agency

■ Evaluation:

- **Dossier evaluation:** The Member States authorities can check the compliance of any registration dossier with the requirements of REACH, and examine and endorse the testing proposals provided by the industry.
- **Substance evaluation:** The Member State authorities are allowed to examine registration dossiers in order to evaluate whether a substance presents a risk to human health or the environment

■ Authorization:

- **Authorisation** will be required for each use of substances of very high concern:- CMRs, PBTs, vPvBs etc. identified as causing serious and irreversible effects on humans and the environment.
- **Authorisation** will be granted for these uses if the manufacturer or importer is able to demonstrate that risks can be adequately controlled.

Short description of REACH principles

- Planned EU regulation for Registration, Authorization and Evaluation of Chemicals
- Leading principle: reversal of 'burden of proof' from authorities to industry
- Chemicals include all substances & substances in preparations manufactured, imported or used downstream
- Encompasses (at least) approx. 30.000 substances on the EU market
- Aims at improving safety to health & environment by filling data gaps, demanding authorization for chemicals of concern and fostering substitution
- Data requirements mainly tonnage triggered: 4 volume bands >1 <10 t/a; >10<100 t/a; >100<1.000 t/a; >1.000 t/a + substances of very high concern (SVHC)
- Exemptions for groups like polymers and limited requirements e.g. for intermediates
- Data sharing mandatory among all registrants of a substance

Different positions on REACH:

a) The European Commission REACH objective

- "This Regulation should ensure a high level of protection of human health and the environment as well as the free movement of substances, on their own, in preparations and in articles, while enhancing competitiveness and innovation."

Preface of "REGULATION (EC) No .../2006 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

b) Alliance of Small and Medium Enterprises

- **“Countless jobs are at stake** in our companies and in those of our customers in other EU member states. If no workable solution for SMEs can be found, REACH will result in the disappearance of many substances from the market, will seriously impact innovation efforts and thus restrict our future know-how – the essence of life for our industry. And if no practicable registration and authorisation regulations are put in place, we strongly expect REACH to have a counterproductive effect with regard to the protection of the environment, consumers and occupational health – even for animal experiments.” [September 2006]

The logo consists of the word "OBJECT!ON" in a bold, black, sans-serif font. The exclamation mark is red and positioned between the "T" and "O". The entire logo is set against a light gray oval background.

No to an unrealistic EU chemicals policy

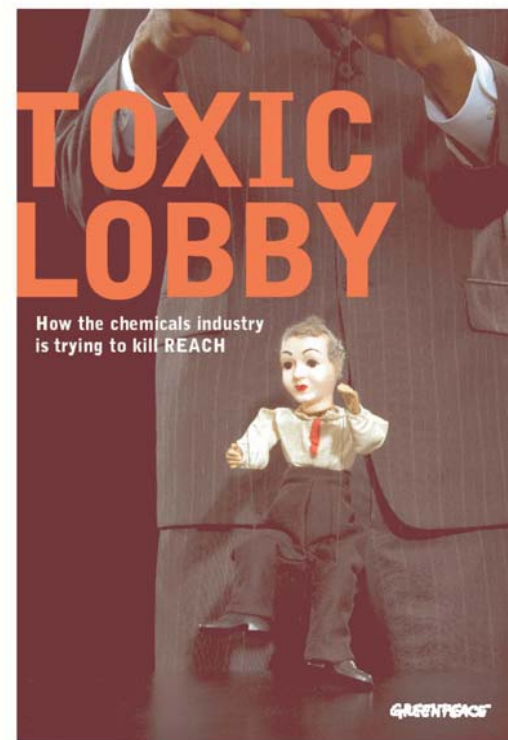
The Alliance of Small and Medium-sized Enterprises

c) Greenpeace 2006 [May 2006]

REACH



REACH:
Die Entscheidung naht ...
REACH kommt !!!



*Relevant steps in legislation 2006/7 until EIF**

- **June 2006:** common position of the European Council adopted
- **September 11:** deadline for proposed amendments by the European Parliament (EP)
- **October 10:** voting by EP Committee Environment (ENVI)
- **November:** 2nd reading by the European Parliament:
 - EP can approve common position: **REACH is adopted**
 - Reject REACH: **REACH is not adopted**
 - propose amendments (absolute majority required)
- **December:** 2nd reading by The Council
 - Council can approve amendments: **REACH is adopted**
 - Council does not approve amendments: conciliation procedure
- **'Conciliation committee' (only if required):**
 - Agrees on joint text: **REACH is adopted**
 - Does not agree on joint text: **REACH is not adopted**
- **April 2007 (or later?): expected REACH entry into force**

*) EIF = entry into force

The REACH registration timeline after EIF

- April 2007: expected date for REACH entry into force (EIF)
- + 12 months: European Chemical Agency (ECA) in Helsinki operational
- + 6 months: deadline for pre-registration:
 - All substances per legal entity manufactured or imported
 - small set of information per substance
 - Publication of all pre-gistered substances via Internet
 - Information to all common users of a substance (= SIEF members)
- +18 months: deadline for registration:
 - All substances > 1.000 t/a + substances of very high concern
 - Chemical safety assessment + chemical safety report required if not exempted / waived
- + 36 months: deadline for registration:
 - All substances > 100 < 1.000 t/a
 - Reduced set of information required compared to substances > 1.000 t/a
- + 60 months: deadline for registration:
 - All substances > 1 < 100 t/a
 - Reduced set of information required compared to substances > 100 t/a

11 years period
to fully implement
REACH

Duties & obligations of a manufacturers

- Pre-register all phase-in substances subject to REACH per legal entity
- Collect all information available for these substances
- Prepare registration dossier according to requirements depending on volume band or risk potential
- Enter substance data into IUCLID 5 (deadlines defined by volume bands or risk potential)
- Share information with all participants of the SIEF (Scientific Information Exchange Forum): OSOR (= one substance, one registration) principle
- Participate in consortia to fill gaps (option)
- Register via consortium or on your own

Duties & obligations of an importers

...are principally the same as those of the manufacturer

but:

■ The importer has some options:

- Ask the supplier outside EU to register via a third party natural or legal person (EU resident)
- Switch to a EU manufacturer who is a registrant
- Manufacture himself in EU instead of importing and register on his own
- Stop using substance in EU....

REACH exemptions

- Pharmaceuticals, pesticides, and radioactive materials
- Substances that enter Europe only in transit to another location
- Non-isolated intermediates (substances that are produced only in the course of creating another substance and never leave the factory)
- Substances that are formed as byproducts, or that result from an incidental chemical reaction, such as exposure of certain chemicals to sunlight
- a variety of natural substances e.g. oils, fatty acids, natural gas, crude oil and coal. Minerals, ores, or substances occurring in nature are exempted if they are not chemically modified during their manufacturing and not dangerous.

The 6 key tasks of Downstream Users (I)

1. DUs may be **any industrial user of chemicals**, whether formulators of preparations (e.g. paint producers) or users of chemicals such as oils and lubricants in other industrial processes
2. DUs are required to consider the **safety of their uses of substances**, based primarily on information from their suppliers, and to **apply appropriate risk management measures**.
3. DUs will need to **communicate effectively with their manufacturers or importers**, to get the information they need in the safety data sheet supplied to them.

Most of ESTAL
members probably are
(also) DUs

The 6 key tasks of Downstream Users (II)

4. DUs have the **right to make their uses known to their manufacturers or importers** so that the manufacturers or importers can include these uses in their chemical safety assessments as “identified” uses
5. A downstream user can also choose to keep his use confidential or decide to use a substance outside the conditions described in an exposure scenario communicated to him. **In these cases he will have to perform a chemical safety assessment himself**
6. If a downstream user is using a substance in quantities starting at 1 t/a per year **outside the conditions described in the exposure scenario communicated to him in the safety data sheet he will need to report his use** in a brief general description to the Agency.

Substances in articles (I)

- **Definition:** *"Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than its chemical composition;"* (REACH, Article 3(3))
- **Article 7 of REACH** means the **registration is obligatory** only for substances in articles and for which the following conditions are met:
 - The substance is intended to be released during normal and reasonable foreseeable conditions of use
 - The total amount of the substance present in the articles exceeds 1 t/a per producer or importer
 - The substance has not yet been registered for that use
- **Notification** is required for substances of very high concern (SVHC) present in articles and for which the following conditions are met:
 - The substances are present in those articles in a concentration above 0.1%
 - The total amount in those articles exceeds 1 t/a per producer or importer

Substances in articles (II)

- Among the objective of REACH is to prevent the import of articles containing substances with potential negative impact on human health and/or environment
- At the same time manufacturers located in the EU shall not suffer competitive disadvantages through the import of articles containing dangerous substances not registered within REACH
- However analytical proof can be extremely difficult esp. for very low concentrations
- A producer outside EU may use a variety of substances non compliant with REACH and therefore less expensive
- and thus get competitive advantage over EU manufacturers
- Problem still unsolved by legislators

Substances in preparations (I)

- REACH knows only the terms
 - “SUBSTANCES” and “SUBSTANCES in PREPARATIONS”
 - Not “products”, “chemicals”, “compositions” etc.
- ‘Phase-in’ substances are those already registered in EINECS
- ‘Non-phase-in substances’ are new chemicals not registered in EINECS or ELINCS
- A preparation in the wording of REACH means a mixture or solution of two or more substances
- Example:
 - If a company manufactures / imports a preparation with say 50 individual substances added ‘on purpose’ 50 (pre-)registrations are necessary
- If the manufacturing of preparations leads to another substance / other substances via reaction(s) also that substance(s) have to be (pre-)registered

Substances in preparations (II)

- If you buy a preparation from a manufacturer or importer located in the EU the individual substances in the preparation will have to be registered by your supplier when it exceeds the 1 t/a threshold
- If you buy a preparation from a downstream user or a distributor located in the EU the substances (> 1 t/a) in the preparation will have to be registered by the M/I at the origin of the European supply chain
- If you import a preparation yourself you will first have to pre-register phase-in substances and register each substance of the preparation if the volume of the substance exceeds 1 t/a (per legal entity) taking into account exemptions/exclusions and deadlines for registration
- In all cases the usage (or use / exposure) category has to be registered

REACH means:

No data – no market!

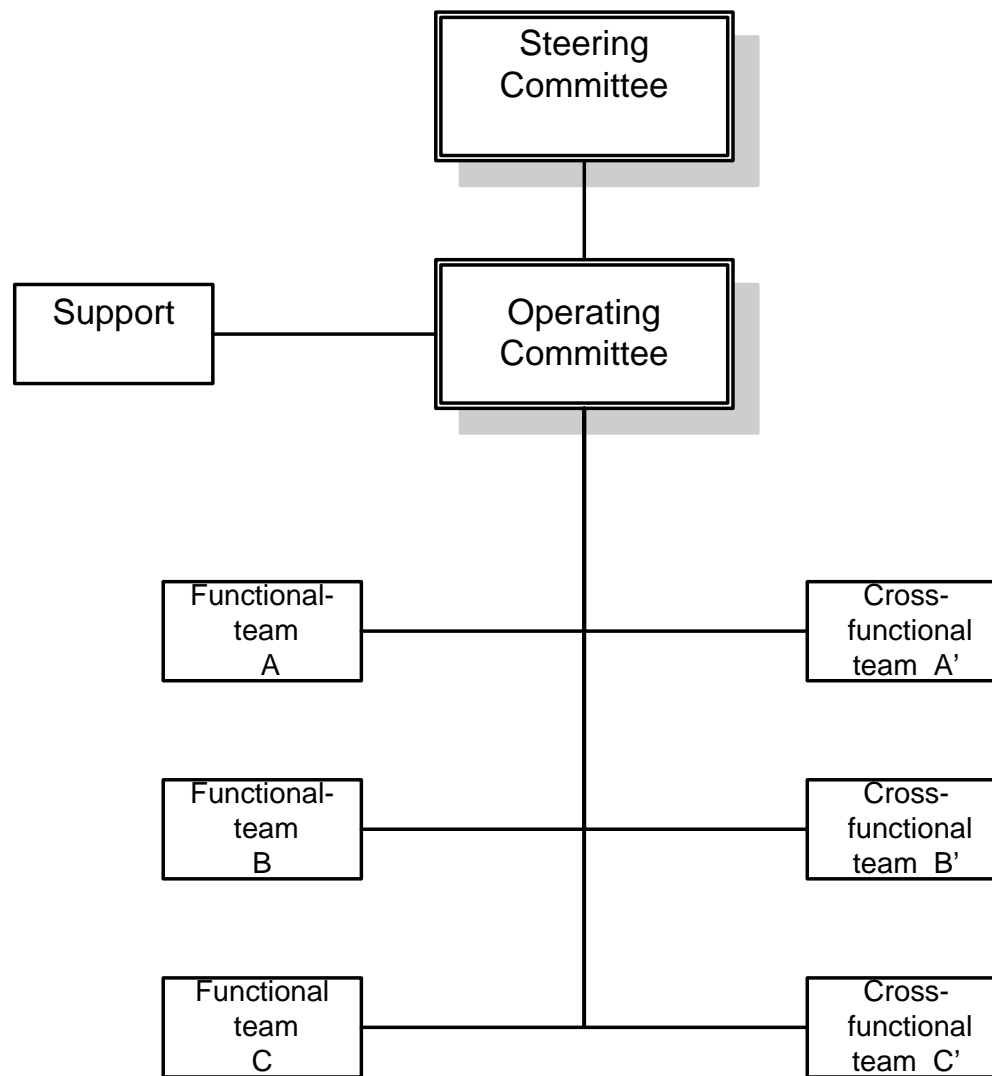
*[REACH proposal, Council common position,
Chapter 2, Article 4a]*



Clariant's position in the supply chain as defined by REACH

- Clariant is
 - **Manufacturer**
 - Inside / outside EU
 - **Importer**
 - e.g. for raw materials, traded or toll manufactured goods
 - **Downstream user**
 - e.g. for raw materials and substances in preparations

Clariant REACH Organization scheme



Clariant's active contribution to REACH

- **Internal organization:**
 - REACH Steering & Operating committees
 - Expert teams
- **Cooperation in chemical federations & associations:**
 - Cefic: REACH Industry Preparation Working Group
 - national federations like VCI, SCGI, FEIQE, UIC, CIA, etc.
 - Industry branch organizations: ETAD, Tegewa, HERA, etc.
- **Participation in REACH related Projects**
 - RIP: '*REACH Implementation Projects*'
 - SPORT: '*S*trategic *P*artnership on *REACH Testing*':
8 companies tested the registration procedure
- **Communication along the supply chain:**
 - Information exchange with 'downstream users' (customers) & suppliers
- **Discussions with stakeholders:**
 - Continual contacts to MEP (Members of European Parliament) of all fractions in different countries

Cefic REACH Industry Preparation Letters: a strongly recommended support!



REACH Industry Preparation Letter No 4

August 2006

REACH Industry Preparation Letter No 4

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REACH: at the end also a chance for industry?

- Knowledge about products will increase:
 - Should reduce potential liability claims in the long run
- 'REACH approved' may become a certificate-like status:
 - e.g. compared with Oeko-Tex 100 label in textiles
- Impact on worldwide chemical legislation:
 - Trend to more rigid implementation of national regulations e.g. in parts of Asia
- Partnerships along the supply chain could be strengthened:
 - e.g. mutual information on uses, applications, exposure scenarios
- Public perception of the chemical industry and partners:
 - REACH could contribute to a better image (hopefully!)

Public

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20.07.2006

Thank you!



Exactly your chemistry.

Disclaimer

- In this presentation reference is made to the 'European Council's common position of REACH of 12 June 2006' [English version]
- This presentation will be updated if necessary until 5 October depending on the 'state of the play' of the legislation process
- The information contained in this presentation is intended for guidance only and whilst the information is provided in utmost good faith and has been based on the best information currently available, is to be relied upon at the user's own risk.
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