



REACH

*Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals
(OJ L 396, 30.12.2006, p. 1–849)*

DG ENTR Unit F1

REACH – Outline.

- 1. Introduction about REACH.*
- 2. REACH establishes the EU Chemicals Agency.*
- 3. REACH provides obligations with processes for*
 - (a) Registration of substances;*
 - (b) Evaluation;*
 - (c) Authorisation;*
 - (d) Restrictions of certain substances and mixtures;*
 - (e) Information in the supply chain and data sharing.*
- 4. Enforcement of REACH.*
- 5. Concluding remarks.*

1. Introduction: what is REACH?

- **REACH** = EU Regulation that concerns the **Registration, Evaluation, Authorisation and Restriction of Chemicals**.
- **REACH places greater responsibility on industry** to manage the risks that chemicals may pose to health and the environment. In principle REACH applies to **all chemicals**.
- **Legal basis:** Article 114 TFEU of the Treaty of Lisbon (ex-Article 95 EC Treaty)

REACH is an EU Regulation ➡ it is binding in its entirety, directly applicable to all EU MS. **Transposition is not required.**

Implications for the accession countries:

set the necessary administrative capacities

inform the industry/other stakeholders about REACH.

1. Introduction: Objectives

Article 1 - Aims of REACH

- *ensure a **high level of protection** of human health and the environment,*
- *the promotion of **alternative methods** used for the assessment of hazards of substances,*
- *the free circulation of substances on **the internal market**,*
- *enhance **competitiveness and innovation**.*

2. European Chemicals Agency

REACH establishes **European Chemicals Agency (ECHA)**:

- *central coordination and implementation role in the overall processes provided by REACH.*
- *Headquarters: Helsinki, Finland www.echa.europa.eu*

Composition:

- *Management Board,*
- *Executive Director*
- *Committee on risk assessment,*
- *Committee on socio-economic analysis*
- *Member State Committee,*
- *Forum for exchange of information on enforcement activities,*
- *Secretariat that provides technical, scientific and administrative support for the Committees,*
- *Board of Appeal.*

2. REACH committees / expert fora

- **Expert groups at Commission level:**
 - Competent authorities for REACH and CLP (CARACAL)
 - ESPG-REACH
- **Expert committees at ECHA level:**
 - Committee on risk assessment
 - Committee on socio-economic analysis
 - Forum for the enforcement of REACH and CLP
- **Decision-making fora:**
 - Commission:** REACH Committee (Comitology)
 - ECHA:** Member States Committee.

3. (a) Registration of substances

Article 5 : "no data, no market".

Registration - obligation for the industry – conditions:

- *EU Manufacturers and importers of chemicals*
- *Substances produced or imported in EU in quantities of 1 tonne or more per year per company*
- *A substance per registration dossier submitted to ECHA*
- *Within a specific deadline depending on the quantity.*

3. (a) Registration of substances - Deadlines:

- 1) **1st December 2010:** *more than 1.000 tonnes per year (plus some substances in lower quantities with a very specific classification e.g. carcinogenic).*
- 2) **1st June 2013:** *all substances manufactured and imported in more than 100 tonnes per year.*
- 3) **1st June 2018:** *all substances manufactured and imported in more than 1 tonne per year.*

Existing substances (so called phase-in substances) - do not have to be registered at once:

- **transitional regime** for them, if they were **pre-registered** between 1st June and 1st December 2008.

In exceptional cases, also a later pre-registration is possible.

3. (b) Evaluation - procedures

- ***Dossier evaluation:***

ECHA may evaluate a **registration dossier** to check whether it is compliant with REACH.

ECHA must evaluate **all testing proposals** to ensure that unnecessary testing, especially on animals, is avoided.

- ***Substance evaluation:***

Where appropriate, MS competent authorities may also select substances for a broader **substance evaluation** to further investigate substances of concern which are placed on the EU rolling action plan (CoRAP).

3. (c) Authorisation process

Aims:

- *ensuring that risks from substances of very high concern are properly controlled, and*
- *progressively substituted by safer substances or technologies, when these are economically and technically viable.*

Steps:

- *Identification of substances and inclusion in **the candidate list** and progressively listed in **Annex XIV** to REACH.*
- ***Industry must submit applications to ECHA on authorisation** for continued use of these substances:*
 - *Need to demonstrate that the required safety measures have been taken to adequately control the risks, or*
 - *that the benefits for the economy and society outweigh the risks.*

*Where feasible alternative substances or techniques exist, a **timetable for substitution** will also have to be submitted.*

3. (d) Restrictions

- *The restriction process is provided by REACH to regulate the manufacture, placing on the market or use of certain substances, if they pose an **unacceptable risk** to health or the environment.*
- *Restrictions are listed in **Annex XVII** to REACH.*

3. (e) Information in the supply chain & data sharing

- *Manufacturers and importers must **provide their downstream users with information** they need to use a substance safely (e.g. risk management measures).*
- *This will be done via the **classification and labelling system** of chemicals (CLP Regulation) and **Safety Data Sheets (SDS)**, where needed.*
- ***Related EU legislation:***

CLP Regulation – Regulation (EC) No. 1272/2008 on classification, labelling and packaging of substances and mixtures.

3. Exemptions

Substances can be exempted from all or part of the obligations under REACH.

Examples:

- *Article 2 of REACH - Radioactive substances, waste, substances used in the interests of defence, etc.*
- *Article 9 of REACH - Exemption from the general obligation to register for product and process oriented research and development.*

3. Guidance for REACH

- **Information about REACH:**

http://ec.europa.eu/enterprise/sectors/chemicals/reach/index_en.htm

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

- **ECHA Guidance:** Finalised guidance documents are published on ECHA's website:

http://guidance.echa.europa.eu/guidance_en.htm

- **REACH Helpdesks** in each Member State provide advice to industry on their obligations and how to fulfil their obligations under REACH, in particular in relation to registration.

List of helpdesks:

http://echa.europa.eu/help/nationalhelp_contact_en.asp

3. Amendments of REACH and its EU implementing Regulations:

Various amendments of Annexes to REACH since its adoption.

EU Regulations implementing REACH:

- *Regulation (EC) No 340/2008 on the fees and charges payable to ECHA pursuant to REACH;*
- *Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of ECHA;*
- *Regulation (EC) No 440/2008 on the Test Methods pursuant to REACH.*

4. Enforcement of REACH

EU MS authorities are responsible to maintain a system of official controls: inspections/penalties, if non-compliance.

- *Each EU MS designated the competent authority dealing with REACH enforcement.*
- **Penalties** - *each Member State must adopt the penalties that apply to infringement of REACH provisions & must implement them.*

- **ECHA's Forum for exchange of information on Enforcement**

Composition: *MS national enforcement authorities.*

Role: *coordination of enforcement activities - establish a good cooperation, coordination and exchange of information between the Member States, ECHA and the Commission.*

5. REACH - Conclusions

Thank you