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) R****egistration of substances;*
- ***(b) E****valuation;*
- ***(c) A****uthorisation;*
- ***(d) R****estrictions of certain substances and mixtures;*
- ***(e) I****nformation 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* ***R****egistration,* ***E****valuation,* ***A****uthorisation and Restriction of* ***Ch****emicals.*
- ***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

Questions & Answers session

Thank you

DG ENTR Unit F1