EUROPEAN REACH REGULATION

SEMINAR ON REACH REGULATION

REACH APPLICATION BY RELEVANT AUTHORITIES

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EUROPEAN LEGISLATION FRAMEWORK BEFORE REACH

Basic horizontal legislative instruments:

- Directive 67/548 (classification, packaging and labelling of dangerous substances)
- Directive 76/769 (limits on the trade and use of dangerous substances and preparations)
- Regulation 793/93 (evaluation and risk control of existing substances)
- Directive 1999/45 (classification, packaging and labelling of dangerous preparations)

FAILURES OF THE EUROPEAN LEGISLATION FRAMEWORK BEFORE REACH

- **Partial focus**: public health protection / workers / environment.
- **Lack of information on risks**: 2.600 substances of more than 1,000 t/year, only 3% of which had been categorised as full risk.
- **Onus of proof**: responsibility of the Administration (nearly always a lack of resources), not of the companies.
- **Lack of transparency**: limited public access to information.
- **Regulative Complexity**: more than 40 directives and regulations.
- **Policy of control**, but not of prevention.

FAILURES OF THE EUROPEAN LEGISLATION FRAMEWORK BEFORE REACH

- Before being able to prohibit or restrict the use of any substance a complete analysis to evaluate the risks had to be completed.
- The evaluation of the substances is a very complex study. Nearly always some data is missing. New information request procedures are very slow.
- As for the evaluation, information was only requested from producers and importers, but not from intermediate users. Lack of knowledge of the final destination of the substances; lack of knowledge of exposure, a vital factor for the evaluation.

BALANCE OF THE EUROPEAN LEGISLATION FRAMEWORK BEFORE REACH

- Slow
- Numerous resources required
- Inadequate assignation of responsibilities and difficulty in the realisation of complementary testing.
- 2 different jurisdictional regimes implied, according to whether existing substances were involved (the 100.016 under EINECS) for which very little information was required, or the 3.000 new substances (under ELINCS)

Given the results obtained (very few substances evaluated), the balance can be considered to be unsatisfactory.

GENERAL PRINCIPLES OF REACH

➢ OBJETIVES

- ✓ Guarantee a high level of protection for public health and the environment
- ✓ Promote alternative methods for the evaluation of the risks of substances
- ✓ Free circulation of substances within the internal market
- ✓ Promote competitiveness and innovation

➢ AREA OF APPLICATION

- ✓ Substances as such, in the form of preparations or contained in articles

➢ ADDRESSED TO

- ✓ Manufacturers, importers and intermediate users

REACH
PRINCIPLE ACTIONS

- Registry of substances above 1 tonne in weight
- Evaluation by the Agency and the Member States
- Authorisation of substances of very high concern
- Restrictions – the security network
- Agency to manage the system

REACH
PRINCIPLE ACTIONS

Enter in to force - 1st June, 2007.

However, the majority of its dispositions are applied at a later date:

- **1st June 2008**:
  - ✓ Pre-registry of substances transitory phase.
  - ✓ IDOPP
  - ✓ Registry of non pre-registered substances
  - ✓ Evaluation and authorisation
  - ✓ Obligations of intermediate users
- **1st June 2009**:
  - ✓ New procedure of restrictions.
- **1st Dec 2010**:
  - ✓ Obligations of classification and labelling

REACH
PRINCIPLE ACTORS

- **Industry**
- **Administration**
  - ✓ Commission
  - ✓ European Chemicals Agency (ECHA)
  - ✓ Member States
- **Third parties implicated**

ECHA. EUROPEAN CHEMICALS AGENCY - OBJECTIVES

The REACH Regulations create a European Chemicals Agency (ECHA):

- Manage and in some cases, execute the technical, scientific and administrative aspects of the Regulations
- Guarantee coherence of application at community level

ECHA. EUROPEAN CHEMICALS AGENCY - TASKS

- Contribute the technical and human resources to carry out good management of the technical, scientific and administrative aspects of REACH
- Provide scientific assessment
- Management of the database, documentation and guides based on informatics technologies
- Support the national helpdesks and offer assistance services to industry
- Make information on chemical substances available to the public

ECHA. EUROPEAN CHEMICALS AGENCY - COMMITTEES

- Management Board
- Executive Director (ED)
- Risk Analysis Committee (RAC)
- Socio-Economic Analysis Committee (SEAC)
- Member States Committee (MSC)
- Forum for Exchange of Information (Forum)
- Board of appeal
- Secretary

MEMBER STATES OBLIGATIONS

- Designation of the Competent Authority
  - ✓ **(RD 1802/2008, BOE nº 266 de 4.11.08)**
- Designation of national representatives in ECHA organs
- National helpdesk services
  - ✓ **(art. 124 REACH and art. 44 CLP)**
- Enforcement: Official control
  - ✓ **(art. 125 REACH and art. 46 CLP)**
- Provisions on penalties
  - ✓ **(art. 126 REACH and art. 47 CLP)**

RELEVANT AUTHORITY TASKS
SUPPORT TO THE ORGANS OF ECHA

- **MANAGEMENT BOARD**: Spanish representative from the Environment Ministry
- **RAC**: Spanish representative from the Ministry of Health and Spanish representative from the Ministry of the Environment
- **SEAC**: Spanish representative from the Ministry of Industry
- **MEC**: Spanish representative from the Health Ministry
- **Forum**: Spanish representative from the Health Ministry

RELEVANT AUTHORITY TASKS REGISTRATION

- Receive information from the ECHA on the pre-registered substances and the companies identified in the country
- Receive information from the ECHA on the registry dossiers and their updating (June 2008) **(art.20, 22)**
- Make observations on the Agency's decisions in relation to the exemptions to the registry of substances oriented to PPROD that are manufactured or imported in the country (June 2008) **(art.9)**

RELEVANT AUTHORITY TASKS
EVALUATION

- **Evaluation of the dossiers:** (competence of the ECHA)
  - ✓ The CAs receive the information and propose modifications.
- **Evaluation of substances:** (competence of the MS)
  - ✓ AC and ECHA: priorities criteria. Community mobile action plan. First plan before del 1.12.2011.
  - ✓ AC: Proposals for the inclusion of substances in the Mobile Action Plan
  - ✓ AC select the substances to be evaluated. Period of evaluation, 12 months (1.12.2012). Resulting information for processes of authorisation and restriction (from 2012).
  - ✓ AC: evaluation of any intermediate substance from its country (from 2008).
  - ✓ AC: observations on the projects for decision elaborated by the rest of the Member States (from 2012).

RELEVANT AUTHORITY TASKS
AUTHORISATION

- MS and the Agency can present a dossier in accordance with Annex XV to include substances on the “candidates list”.
- Formulate observations on any dossier presented by other Member States or the Agency itself (from 2009).
- Comment on the opinions of the Risk Analysis and the Socio-Economic Analysis Committees.

RELEVANT AUTHORITY TASKS
RESTRICTION

- MS and the Agency can present a dossier in accordance with Annex XV (from 1.06.09)
- Formulate observations on any dossier presented other Member States or the Agency itself
- Participate in the Risk Analysis and the Socio-Economic Analysis Committees

RELEVANT AUTHORITY TASKS
CLASSIFICATION and LABELLING

- Present proposals to the Agency on the harmonised classification and labelling system according to Annex XV **(art. 111 REACH)**
- Receive proposals from the industry on changes to the harmonised classification and labelling system (CLP Regulation)
- Evaluate the requests from the industry on the use of alternative names on the labelling of products (CLP Regulation)
- Pending tasks:
  - ✓ Translate the names of the substances in Annex VI of the del CLP Regulation to the languages of the MS
  - ✓ Promote the standardisation of criteria for the classification and labelling of PBT and vPvB at UN (GHS) level.

RELEVANT AUTHORITY TASKS
INFORMATION

- Every 5 years, produce a report on the functioning of the REACH Regulations (1st in June, 2010) and the CLP Regulation
- Continuous exchange of information with the Agency and other MS on new risks data
- When necessary, inform the population of risks resulting from the substances.

RELEVANT AUTHORITY TASKS
COMPLIANCE

- The Member States will maintain a System of official controls and other activities (from 2007) **(art. 125)**

- The MS will establish provisions on penalties apllicable for infringement of the provisions of the Regulation and shall take all measures necessary to ensure their application. The penalties provided for, must be effective, proportionate and dissuasive (before 1.12.08) **(art.126)**

- In Spain, the Ministry for the Environment, Rural and Marine Affairs, and the Ministry for Health and Social Policy have elaborated a Law pre-project which will establish the Regime of penalties (presently in the approval phase)

RELEVANT AUTHORITY TASKS
ASSISTANCE SERVICES

- **Helpdesk of the ECHA**
- **National Helpdesk** : (27 EM)

1. **REACH Help-Net**
   - ✓ REHCORN: (REACH Helpdesk Correspondent Network): Representatives of the 27 MS, ECHA, IS, LI, NO and industry observers
   - ✓ RHEP: (REACH Helpdesks Exchange Platform): Computer application to create a new database and undertake consultations between the Member States and the ECHA

2. **CLP Help-Net:**(27 MS + ECHA + IS + LI + NO)
   - ✓ Standardise responses
   - ✓ Promote assistance
   - ✓ Identify problems

RELEVANT AUTHORITY TASKS
SPANISH HELPDESK

CLP

Regulation
EC Nº 1272/2008
Art. 44

REACH

Regulation
EC Nº 1907/2006
Art. 124

Royal Decree
1802/2008

PIRYC
Information portal
REACH y CLP

Competent Authorities in Spain:

Ministry of Health and Social Policy

Ministry of Environmental, Rural and Marine Affairs

RELEVANT AUTHORITY TASKS
SPANISH HELPDESK

PIRYC

(Spanish Information Portal REACH and CLP)

http://portalreach.info/reach/w/

- Scientific-technical support
- Elaboration of guide documents and application manuals
- Assistance to the Business sector and, in particular, small and medium sized companies, for REACH and CLP and other regulations
- Development of specific scenarios for Spanish conditions
- Information to the public
- Connection with the ECHA

INFORMATION PAGES

http://www.echa.europa.eu/reach/legislation_en.asp

http://echa.europa.eu/home_en.asp

http://www.reach-pir.es

http://portalreach.info/reach/w/legislacion

THANK YOU FOR YOUR ATTENTION!