WORKSHOP ON REACH REGULATION

REACH IMPLEMENTATION BY EU MEMBER STATE COMPETENT 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 (restrictions on the marketing and use of certain dangerous substances and preparations)
- Regulation 793/93 (evaluation and control of the risks of existing substances)
- Directive 1999/45 (classification, packaging and labelling of dangerous preparations)

FAILURES IN 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% had been fully assessed.
- **Burden of proof**: responsibility of the Administration (nearly always with lack of resources), not of the companies.
- **Lack of transparency**: limited public access to information.
- **Regulatory 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 ban or restrict the use of any substance a complete analysis to assess the risks had to be completed.
- The evaluation of the substances is a very complex task. Nearly always some data are missing. New information request procedures are very slow.
- As for the evaluation, information was only requested from manufacturers and importers, but not from downstream users. Lack of information on the final destination of the substances; lack of knowledge on exposure (a key issue for the evaluation).

CONCLUSIONS ON THE EUROPEAN LEGISLATION FRAMEWORK BEFORE REACH

- Slow procedure
- A lot of resources required
- Inadequate assignation of responsibilities and difficulty in carrying out complementary testing.
- 2 different legislatives regimes applied depending on whether there were existing substances involved (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 as not satisfactory.

GENERAL PRINCIPLES OF REACH

OBJECTIVES

- ✓ Ensure a high level of protection of human health and the environment
- ✓ Promote the development of alternative methods for the assessment of hazard of substances
- ✓ Free circulation of substances within the internal market
- ✓ Enhance of competitiveness and innovation

SCOPE

- ✓ Substances on their own, in preparations and contained in articles

ADDRESSED TO

- ✓ Manufacturers, importers and downstream users

REACH
MAIN ACTIONS

- Registry of substances above 1 tonne per year
- Evaluation by the Agency and the Member States
- Authorisation of substances of very high concern
- Restrictions – the security network
- Agency to manage the system (ECHA)

REACH
MAIN ACTIONS

Entry into force - 1st June, 2007.

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

- **1st June 2008:**
  - ✓ Pre-registry for phase-in substances.
  - ✓ Notification of PPORD **(Product and Process Orientated Research and Development)** substances.
  - ✓ Registry of non pre-registered substances
  - ✓ Evaluation and Authorisation
  - ✓ Obligations of Downstream users
- **1st June 2009:**
  - ✓ New restrictions process.
- **1st December 2010:**
  - ✓ Obligations on classification and labelling

REACH
MAIN ACTORS

- **Industry**
  - ✓ Manufacturers (M)
  - ✓ Importers (I)
  - ✓ Downstream users (DU)
- **Administration**
  - ✓ Commission (COM)
  - ✓ European Chemicals Agency (ECHA)
  - ✓ Member States (MS's)
- **Third parties involved**
  - ✓ NGO's
  - ✓ Consumers Associations
  - ✓ General Public

ECHA
EUROPEAN CHEMICALS AGENCY

The REACH Regulation creates a European Chemicals Agency (ECHA).

Objectives:

- Manage and in some cases, execute the technical, scientific and administrative aspects of the Regulation

- Guarantee coherence of application at Community level

ECHA
EUROPEAN CHEMICALS AGENCY

Tasks of the ECHA:

- Contribute with 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 guidance based on informatic 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 (MB)
- Executive Director (ED)
- Risk Assessment Committee (RAC)
- Socio-Economic Analysis Committee (SEAC)
- Member States Committee (MSC)
- Forum for Exchange of Information on Enforcement (Forum)
- Board of Appeal
- Secretary

MEMBER STATES OBLIGATIONS

- Designation of the Competent Authority **(Spain by Royal Decree 1802/2008, BOE nº 266 de 4.11.08):**
  - ✓ **Ministry of Heath and Social Policy**
  - ✓ **Ministry of the Environment, and Rural and Marine Affairs**
- Designation of national representatives in ECHA Committees
- Establishment of a National helpdesk service
  - ✓ **(Art. 124 REACH and Art. 44 CLP)**
- Enforcement: Official control and other activities
  - ✓ **(Art. 125 REACH and Art. 46 CLP)**
- Lay down provisions on penalties
  - ✓ **(Art. 126 REACH and Art. 47 CLP)**

SPANISH COMPETENT AUTHORITIES TASKS TO SUPPORT ECHA

- **MANAGEMENT BOARD**: Spanish representative from the Ministry of Environment
- **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
- **MSC**: Spanish representative from the Health Ministry
- **Forum**: Spanish representative from the Ministry of Health

MAIN COMPETENT AUTHORITY TASKS
1- 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 Agency's Decisions in relation to the exemptions to the registry of substances used for product and process orientated research and development (PPORD) that are manufactured or imported in the country (June 2008) **(Art.9)**

MAIN COMPETENT AUTHORITY TASKS
2- EVALUATION

- **Evaluation of the dossiers:** (competence of the ECHA)
  - ✓ CA's receive the information and propose modifications.
- **Evaluation of substances:** (competence of the MS's)
  - ✓ CA's and ECHA: prioritisation criteria. Community Rolling Action Plan (CRAP). First plan before 1 December 2011 **(Art. 44)**
  - ✓ CA's: Proposals for the inclusion of substances in the Rolling Action Plan (CRAP)
  - ✓ CA's select the substances to be evaluated. Period of evaluation, 12 months (1 Dec 2012). Resulting information for processes of authorisation and restriction (from 2012).
  - ✓ CA's: evaluation of any intermediate substance from the country where the site is located (from 2008) **(Art. 49)**.
  - ✓ CA's: observations on the projects for decision elaborated by the rest of the Member States (from 2012).

MAIN COMPETENT AUTHORITY TASKS
3- AUTHORISATION

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

MAIN COMPETENT AUTHORITY TASKS
4- RESTRICTION

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

MAIN COMPETENT AUTHORITY TASKS
5- CLASSIFICATION & LABELLING

- May submit proposals to the Agency for harmonised classification and labelling in accordance with 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 CLP Regulation into the languages of the MS's
  - ✓ Promote the standardisation of criteria for the classification and labelling of PBT and vPvB at UN (GHS) level.

MAIN COMPETENT AUTHORITY TASKS
6- 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's on new risks data
- When necessary, inform the population of risks resulting from the substances.

MAIN COMPETENT AUTHORITY TASKS
7- ENFORCEMENT

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

- MS's will establish provisions on penalties applicable 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 of the Environment, and Rural and Marine Affairs, as well as the Ministry for Health and Social Policy have elaborated a blueprint for law which will establish the penalties scheme (at present in the Parliamentary approval phase)

MAIN COMPETENT AUTHORITY TASKS
8- "REACH ENFORCE 1"

- European project to analyse the REACH application 2008-2010

- 1st project of the FORUM program on harmonized inspection. Objectives:

  - ✓ Enhance shared responsibility on REACH
  - ✓ Assess the harmonised performance of manufacturers / importers

- The results of the project will be collected by the end of 2009 and the Forum Working Group will analyse the results and produce a report in early 2010.

MAIN COMPETENT AUTHORITY TASKS
8- "REACH ENFORCE 1"

- **Focus on phase-in substances**
  - ✓ Check that phase-in substances have been pre-registered by the responsible companies
  - ✓ Check that enterprises identify properly their obligations in relation to communicate information of the substances up and down the supply chain (conclusive for registry obligations)
  - ✓ Inspection of as many companies possible in each Member State
  - ✓ Companies will be previously informed of the inspection via a formal letter

MAIN COMPETENT AUTHORITY TASKS
8- "REACH ENFORCE 1" (cont.)

Actions to verify

- ✓ Article 5: No data no market
- ✓ Article 6: Obligation to registry substances on their own or in mixtures (formerly called: preparations)
- ✓ Article 7: Registration and notification of substances in articles
- ✓ Article 31: requirements of the SDS (available; in the official language; complying with all information requested and properly organised)

Activities carry out in Spain

- ✓ The 17 Spanish Autonomous Communities are being inspected by our civil servants
- ✓ By 15 October 2009, 9 Spanish Autonomous Communities had inspected a total of 36 companies.

MAIN COMPETENT AUTHORITY TASKS
9- ASSISTANCE SERVICES

- **Helpdesk of the ECHA**
- **National Helpdesk** : (27 MS's)

1. REACH Help-Net

- ✓ REHCORN: (REACH Helpdesk Correspondent Network): Representatives of the 27 MS's, 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's + 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 & CLP

Competent Authorities in Spain:

Ministry of Health and Social Policy

Ministry of the Environmental, and Rural and Marine Affairs

RELEVANT AUTHORITY TASKS
SPANISH HELPDESK

PIRYC

(Spanish Information Portal REACH and CLP)

http://www.reach-pir.es

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

INFORMATION WEB SITES

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!