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European perspective on REACH

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REACH

is the European Community Regulation on chemicals and their safe use (EC 1907/2006).

It deals with the **R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emical substances.

The law entered into force on 1 June 2007.

REACH provisions are being phased-in over 11 years.

5 years review in 2012

AIM

to improve the protection of human health and the environment through the better and earlier identification of the intrinsic properties of chemical substances.

At the same time, REACH aims to enhance innovation and competitiveness of the EU chemicals industry.

The Regulation also calls for the progressive substitution of the most dangerous chemicals when suitable alternatives have been identified.

The benefits of the REACH system will come gradually, as more and more substances are phased into REACH.

INDUSTRY RESPONSIBILITY

The REACH Regulation places greater responsibility on industry to manage the risks from chemicals and to provide safety information on the substances.

- Manufacturers and importers are required to gather information on the properties of their chemical substances, which will allow their safe handling, and
- to register the information in a central database run by the European Chemicals Agency (ECHA)

European Chemicals Agency (ECHA)

Located in Helsinki, Finland, and acts as the central point in the REACH system:

- it manages the databases necessary to operate the system,
- co-ordinates the in-depth evaluation of suspicious chemicals and
- is building up a public database in which consumers and professionals can find hazard information.

REGISTRATION

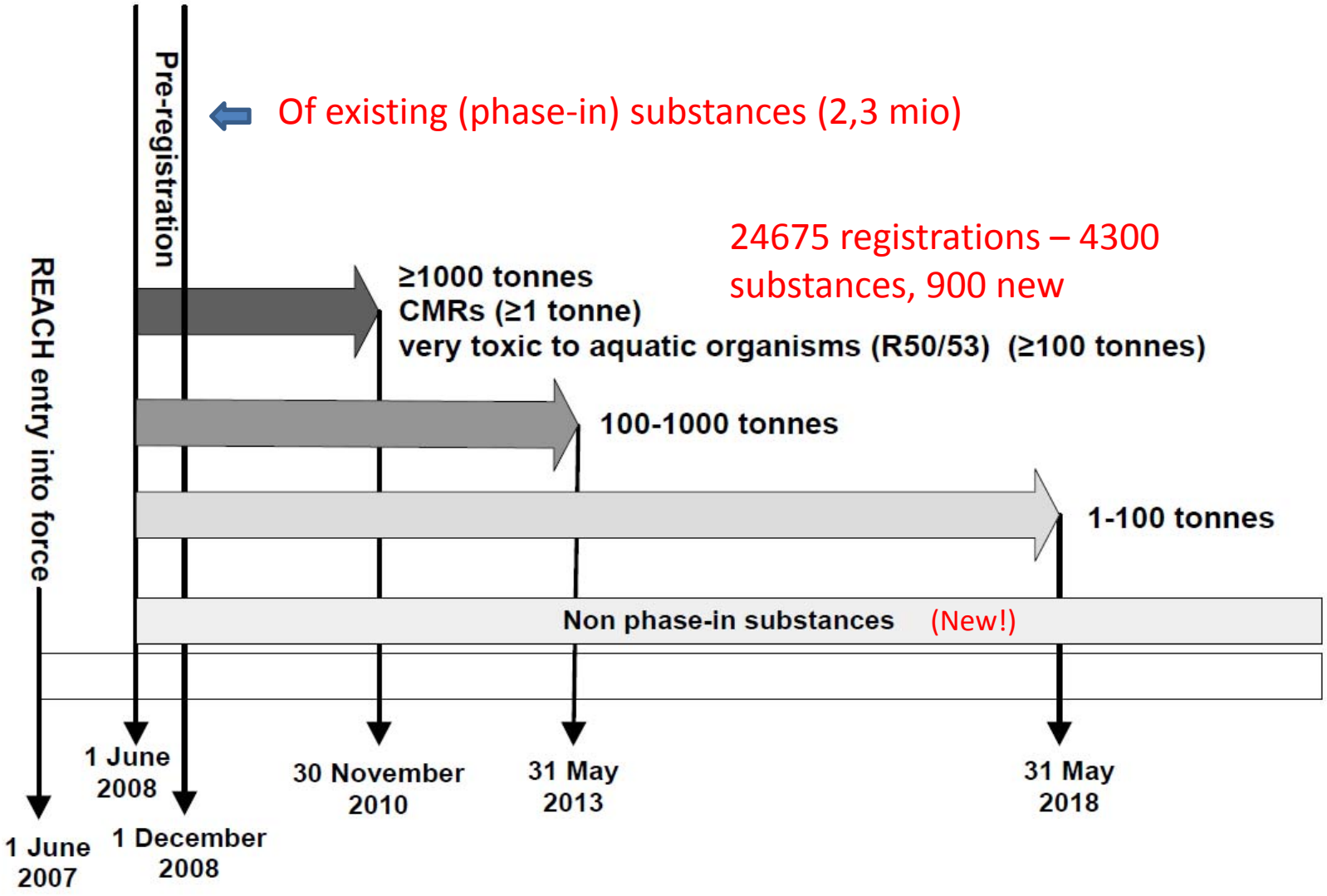
- There is a general obligation for manufacturers and importers of substances to submit a registration to ECHA for each substance manufactured or imported in quantities of ≥1 tonne per year. However some exemptions and phase-in delays.

- If a company in fails to register a substance this company is no longer allowed to manufacture or import this substance.

- Registration means that a manufacturer or importer has provided a registration technical dossier and an additional chemical safety report (if ≥ 10 tonnes) not received any indication that it is incomplete.

- This does not by itself mean that the dossier is in compliance with the legislation nor does it mean all the properties of the registered substance have been identified.

Registration deadlines



DATA SHARING

For both phase-in and non-phase-in substances, data gained by vertebrate animal testing are to be shared, in exchange for payment.

Communication mechanisms are set up to enable manufacturers and importers to reach agreements on the sharing of studies on vertebrate animals.

Information not involving tests on vertebrate animals (e.g. *in vitro* studies and QSARs) must be shared on the request of a potential registrant.

Substance Information Exchange Forum (SIEF)

- Joining a Substance Information Exchange Forum (SIEF) is a legal obligation of all registrants. SIEFs are formed by companies that intend to register the same substance.
- The SIEFs are established to facilitate the sharing of information, avoid duplication of new studies and agree on classification and labelling if necessary.
- SIEF members need to nominate a Lead Registrant to submit the joint registration dossier. 3455 active lead registrants in September 2011.

INFORMATION IN THE SUPPLY CHAIN

The communication requirements of REACH ensure that not only manufacturers and importers but also their customers, i.e. downstream users and distributors, have the information they need to use chemicals safely.

Information relating to health, safety and environmental properties, risks and risk management measures is required to be passed both down and up the supply chain.

Commercially sensitive information is not required to be exchanged.

The primary tool for information transfer is the well-established and familiar safety data sheet (SDS) for all dangerous substances. As more information will be available as a result of registrations the quality of safety data sheets will improve.

EVALUATION

1. **Dossier evaluation**: the Agency will do a quality check of the registration dossiers.

2. **Substance evaluation:** The Agency in co-ordination with the Competent Authorities of Member States may clarify suspicions of risks to human health or the environment by requesting further information from industry

EVALUATION

21 October 2011 ECHA submitted the first draft Community rolling action plan for substance evaluation (CoRAP)

It contained 91 substances that was proposed for review by member states in 2012, 2013 and 2014

The ECHA member state committee will evaluate before February 2012

AUTHORISATION

For substances of very high concern, an authorization is required for their use and their placing on the market.

The substances required to be authorized are substances which are:

- CMR category 1 and 2,
- PBT, vPvBs, and
- Identified from scientific evidence as causing probable serious effects to humans or the environment equivalent to those above on a case-by-case basis, such as endocrine disrupters.

The European Commission will develop guidance to clarify the criteria for such a case-by case

ECHA publish a candidate list of substances meeting the criteria above and reflecting its multiannual work plan, taking into consideration comments from interested parties.

Candidate list

- Substances that are included in the Candidate List have been identified as Substances of Very High Concern (SVHC).
- These substances may have very serious and often irreversible effects on humans and the environment.
- Substances on the Candidate List may subsequently become subject to authorization by decision of the European Commission
- The list will be updated regularly. Per 20 June 2011 it contains 53 substances/groups

AUTHORISATION

The authorization procedure consists of two steps:

1. A committee decides as to which substances on the candidate list will be included in the system (Annex XIV), which uses of the included substances will be exempted from the authorization requirement (e.g. because sufficient controls established by other legislation are already in place) and which deadlines will have to be met. This step is necessary to prioritize substances and to focus resources.
2. Those using or making available a substance included in Annex XIV will need to apply for an authorization for each use of the substance within the deadlines set, including an analysis of possible substitutes and including information on relevant research and development activities, if appropriate.
   - If this analysis shows that suitable alternatives are available then the application must also include a substitution plan.
   - An authorization will be granted if the applicant can demonstrate that the risk from the use of the substance is adequately controlled.
   - If not, then it may also be granted if the socio-economic benefits outweigh the risks and there are no suitable alternative substances or processes.
   - PBTs, vPvBs and those CMR substances for which a safe level cannot be defined, cannot be authorized based on adequate control of risk.

RESTRICTIONS

Any substance on its own, in a preparation or in an article may be subject to Community-wide restrictions if it is demonstrated that risks need to be addressed on a Community wide basis. Thus, the restrictions provisions act as a safety net.

Proposals for restrictions will be prepared by Member States or by ECHA on behalf of the Commission in the form of a structured Dossier.

This Dossier is required to demonstrate that there is a risk to human health or the environment that needs to be addressed at Community level and to identify the most appropriate set of risk reduction measures.

Deadlines for the procedure to prepare a Commission decision are set out in the Regulation. Interested parties will have an opportunity to comment and ECHA will provide opinions on any proposed restriction.

The existing restrictions set out in Directive 76/769/EEC (such as the ban on asbestos and restrictions on the uses of certain azo-dyes) are carried over in a consolidated version into the REACH Regulation.

Classification and Labelling

REACH builds on existing legislation. A requirement for industry to classify and label dangerous substances and preparations according to standard criteria has long been a feature of the EC's chemicals legislation ("67-Directive)").

A classification and labeling inventory ensures that hazard classifications (and consequent labeling) of all dangerous substances manufactured in, or imported into, the EU are available to all with the aim of promoting agreement on the classifications. Industry will be required to submit all its classifications to the Agency, to be included in the inventory by 3 January 2011.

3 114 835 notifications were received, including 107067 distinct substances!!

Most divergences between classifications of the same substance should be removed over time.

In 2009 REACH was complemented by a EU Regulation on classification, labeling and packaging of substances and mixtures (CLP) which incorporates the classification criteria and labeling rules agreed at UN level, the so-called Globally Harmonized System of classification and labeling of chemicals (GHS).

ECHA events

24 - 25 November 2011, Brussels
ECHA-Stakeholder Exchange Network on Exposure Scenarios

2 - 3 February 2012, Helsinki
Lead Registrants' Workshop

23 May 2012, Helsinki ECHA Stakeholders' Day