# *The new regulation REACH*

# *INTRODUCTION*

**Pedro Guerra**

B&B Asesores

Regional Activity Centre for Cleaner Production

# INTRODUCTION

- Regulation (CE) 1906/2006 (REACH) regulates the Registration, Evaluation, Authorization and Restriction of chemical substances and preparations.
- REACH entered into force on June the 1st, 2007 though it is from June the 1st, 2008 when it will begin to meet the requirements.
- The aim of REACH is to ensure a high level of protection of human health and the environment in the European market. REACH will help raise consumer confidence in chemical substances.

B&B Asesores

Regional Activity Centre for Cleaner Production

# SCOPE

- REACH affects all chemical substances, the "new" and the "existing", except those explicitly excluded in the Regulation

**The REACH regulation affects not only the manufacturers/ importers of chemical substances, mixtures and articles but to all users of those substances throughout the supply chain.**

B&B Asesores

Regional Activity Centre for Cleaner Production

# REGISTRATION

- All chemicals except those listed in the regulation as exempt substances that are manufactured or imported to the UE in quantities exceeding 1 ton/year have to be registered under REACH.

- The REACH means for manufacturers and their suppliers to know in great detail all the characteristics of the substances they use, and permanently controlling the risks that may result from its use, for humans and for the environment. REACH requires that depending on characteristics of the substance and depending on the tonnage, the manufacturer or importer provides information in a registration dossier, that must be submitted from June 1st, 2008.

- The regulation represents different requirements depending on whether it is a substance on its own or in preparations or presented in articles, about the quantities manufactured or imported and the hazards of the substance.

B&B Asesores

Regional Activity Centre for Cleaner Production

# EVALUATION

The European Chemicals Agency (ECHA) will evaluate the registration dossier submitted:

- All registration dossier of substances denoted as “substances of very high concern”.
- All dossier submitted individually (opt out from joint submission)
- 5% of the joint submission registration dossiers.

# AUTHORISATION

It will be required an authorization to manufacture, import or use substances within the EU considered as substances of very high concern [carcinogenic, mutagenic, toxic to reproduction (CMR), persistent and bioaccumulative toxic (PBTs), very persistent and very bioaccumulative (vPvB) and those with the same level of concern.

The list of substances requiring authorization will be found in Annex XIV of the Regulation and will be published from November 2009.

B&B Asesores

Regional Activity Centre for Cleaner Production

# RESTRICTION

It is a mechanism to regulate the manufacture, marketing and use of substances that are considered to present an unacceptable risk to health or the environment in the EU.

Substances on their own or their preparations are in Annex XVII, which are the chemicals that have a restriction, they can not be manufactured, marketed or used in the EU unless the conditions of the restriction are fulfilled.

B&B Asesores

Regional Activity Centre for Cleaner Production

# KEY DEFINITIONS

**Substances**: generally defined as chemical elements and their components in naturally or obtained by a manufacturing process.

**Preparations**: are defined as mixtures or solutions of two or more substances (examples: detergents, cosmetics, dyes… )

**Article**: is an object which during production is given a shape, surface or design which determines its function to a greater extent than its chemical composition (eg, candles, pens, razors with lubricating strips, … …)

B&B Asesores

Regional Activity Centre for Cleaner Production

# REACH ROLES

- Manufacturer/ Importer of substances
- Manufacturer/ Importer of mixtures
- Manufacturer/ Importer of articles
- Downstream user : any natural or legal person established within the EU, other than the manufacturer/importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities.
- Distributor: any natural or legal person established within the EU, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties.

B&B Asesores

Regional Activity Centre for Cleaner Production

## PRE-REGISTRATION OF SUBSTANCES

- **From June 1, 2008 to December 1, 2008: Companies could make the pre-registration of phase-in substances.**
- **On 1 January 2009, the Agency published a list of pre-registered substances**
- **The substance / company which is not pre-register can not be qualify to the phase-in regime.**

**PHASE-IN SUBSTANCES ONLY !!!!!**

B&B Asesores

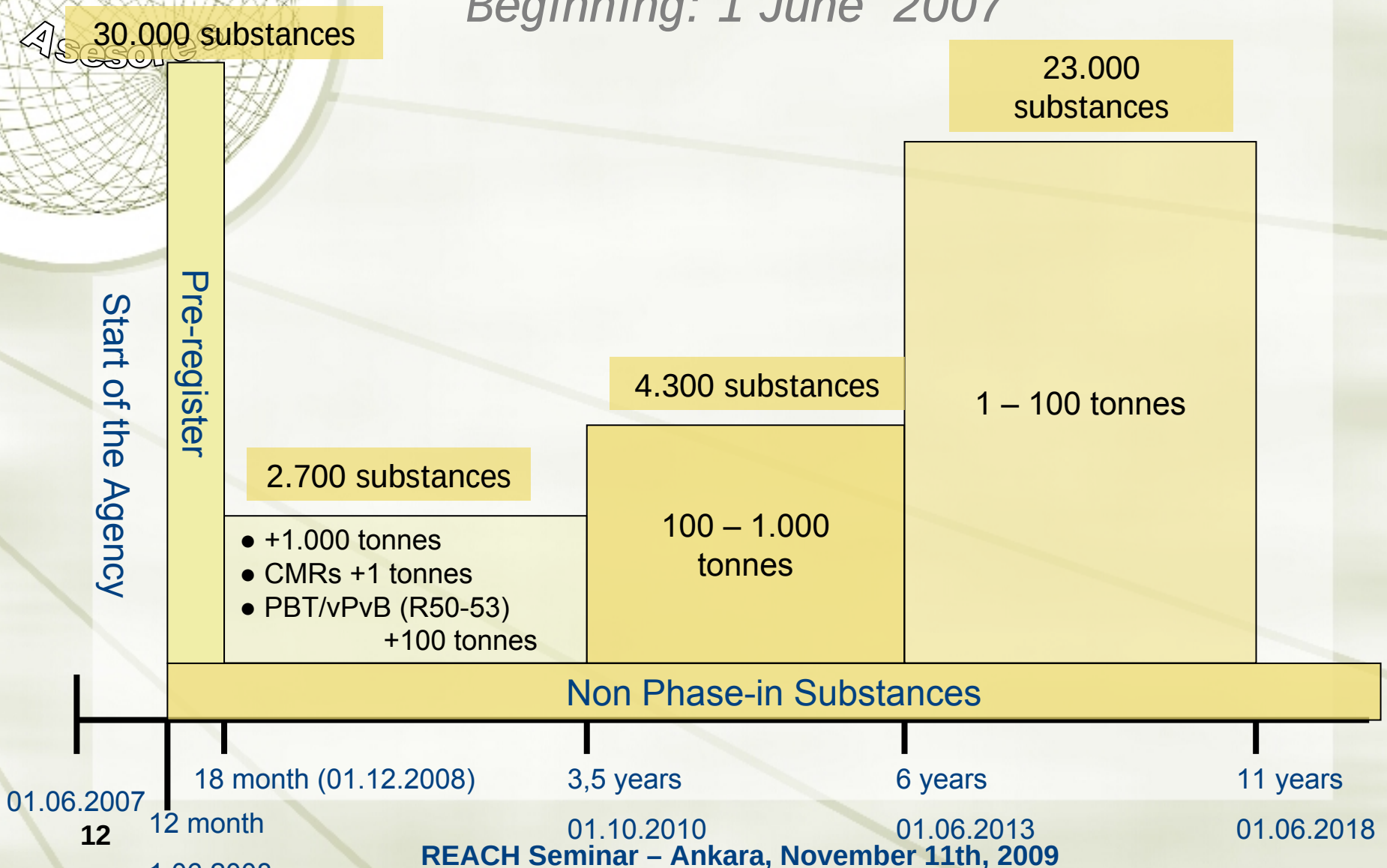
Regional Activity Centre for Cleaner Production

## PHASE-IN SUBSTANCES

- *They are included in the European Inventory of Commercialized Chemical Substances (EINECS). ).*
- *They are included in the NLP list (no-longer polymers)*
- Chemical substances manufactured but not marketed in the EU 15 years before REACH came into force (onsite isolated intermediates or exported substances)

# REGISTRATION SCHEDULE

*Beginning: 1 June 2007*



# CONSEQUENCES OF PRE-REGISTRATION

- The pre-registration dossier is submitted through the REACH-IT platform, from 1 June 2008.
- All the pre-registers become part of a database to share information (SIEF)
- Jointly preparation of the substance registration dossier.

B&B Asesores

Regional Activity Centre for Cleaner Production

If a company has not pre-register a substance, after December 2008, can not sell it in Europe until the registration has been submitted to ECHA.

B&B Asesores

Regional Activity Centre for Cleaner Production

# SUBSTANCE INFORMATION EXCHANGE FORUMS AND CONSORTIA

Once the pre-registration period has finished, the substance information exchange forums (SIEF) is formed, including Manufacturers and Importers of the same substance in order to coordinate the entire registration process.

- At this point, it will be determined the applicable strategy for each company in order to make the process as efficient as possible. Communications and inquiries will begin.

# NON PHASE-IN SUBSTANCES REGISTRATION

The Manufacturers/Importers that have not submitted the pre-registration, (1 T / year) must submit an inquiry for **registration** to the Agency (ECHA).

For non phase-in substances, the registration period began on **1 June 2008. .**

- Non mixtures are registered, only substances
- They must be registered by the Manufacturer or Importer (each substance and for each legal entity)
- They are registered in the European Agency ECHA
- The registration dossier must include the uses of the substance along the entire supply chain in Europe.

B&B Asesores

Regional Activity Centre for Cleaner Production

# SUPPLY CHAIN

# Thank you

Pedro Guerra
B&B Asesores
C/Ganduxer 5-15, L. 5
08021 Barcelona (Spain)
Tel. 932414118
bb@bbasesores.com

Regional Activity Centre
for Cleaner Production
Mediterranean Action Plan
Dr. Roux, 80; 08017 Barcelona
Tel. +34 93 553 87 90
http://www.cprac.org