



What's Next After Pre-registration

19 January 2009



Recap of REACH

- REACH regulation : **R**egistration, **E**valuation and **A**uthorisation of **C**hemicals
- Aim : to improve protection of human health and the environment while enhancing competitiveness of the EU chemicals industry (Article 1)
- No data, no market (Article 5)

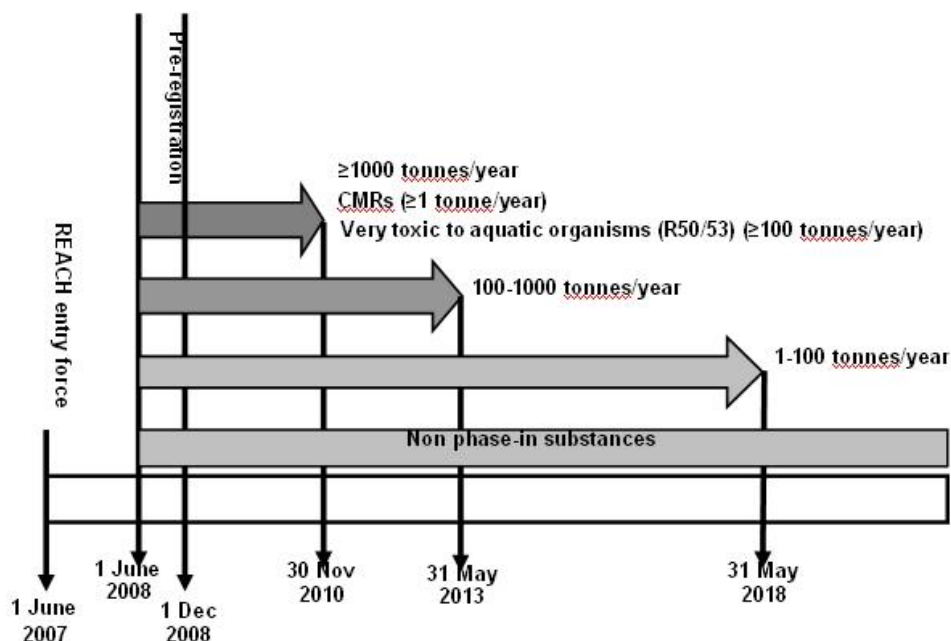


Recap of REACH

- **Registration** – manufacturers or importers concerned to provide registration dossier, indicating the identity of the substances, classification and labelling, guidance on safe use, etc.
- **Evaluation** – ECHA to do a quality check of the registration dossiers and to co-ordinate further risk evaluation of substances
- **Authorisation** – For substances of very high concern (SVHC) being put into a list, an authorisation is required for their use and their placing on the market
- **Restrictions** – Regulate Community-wide conditions for manufacture, placing on the market or use of certain substances where there is an unacceptable risk to human or the environment or prohibit any of these activities



Registration – When?





Pre-registration

Why : To provide a special transition regime for substances which were being manufactured or placed on the market before 1 June 2007 and were not notified according to Directive 67/548/EEC (“Phase-in substances”)

Time : 1 June 2008 – 1 December 2008 (inclusive)

Target : phase-in substances

Do not pre-register on time will not be able to benefit from the transitional regime



Late pre-registration

- Is pre-registration possible for everyone after the 1st December 2008? Yes
- Example: A company has been importing a yearly volume of 200kg of chemical substance until 2009 (not pre-registered because there was no need) In 2009 this company will import > 1 tonne of chemical substance – Registration required
- Late pre-registration



Late pre-registration

- Manufacturers and/or first time importers who produce and/or import phase in substances in quantities of 1 tonne or more after 1st December 2008
- Can still benefit from the prolonged deadlines by doing a **late pre-registration**
- Late pre-registrations can be submitted to the ECHA starting from 5th January 2009



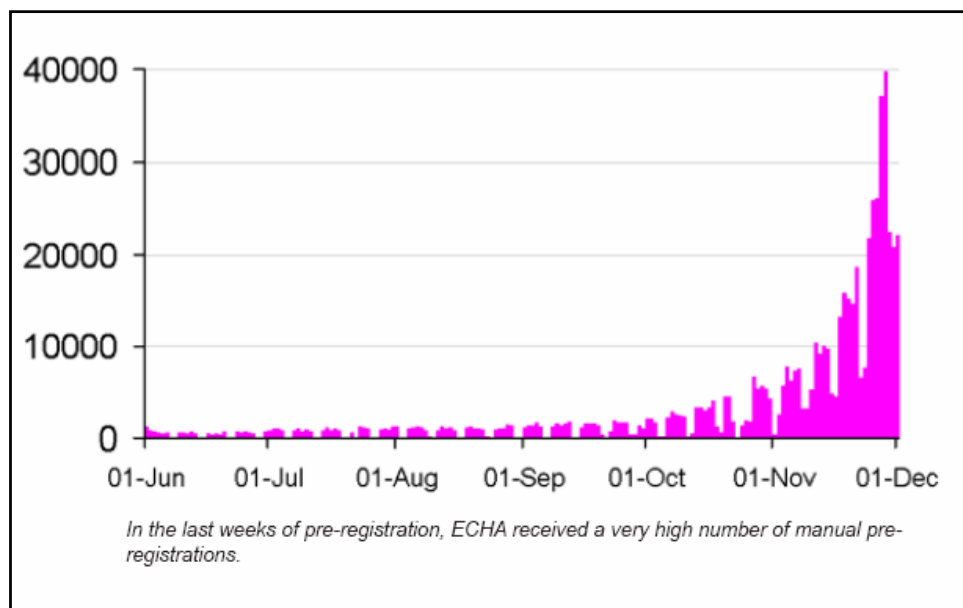
Status of Pre-registration

- ECHA : 15 times more pre-registrations than forecast
- Over 2.6 million, submitted by over 65,000 companies from all EU and EEA countries
- Almost half of the pre-registrations were submitted in the last 2 weeks of the pre-registration period
- All substances have been pre-registered by more than one company

Source : ECHA Newsletter No.3 November/December 2008)



Status of Pre-registration



Status of Pre-registration

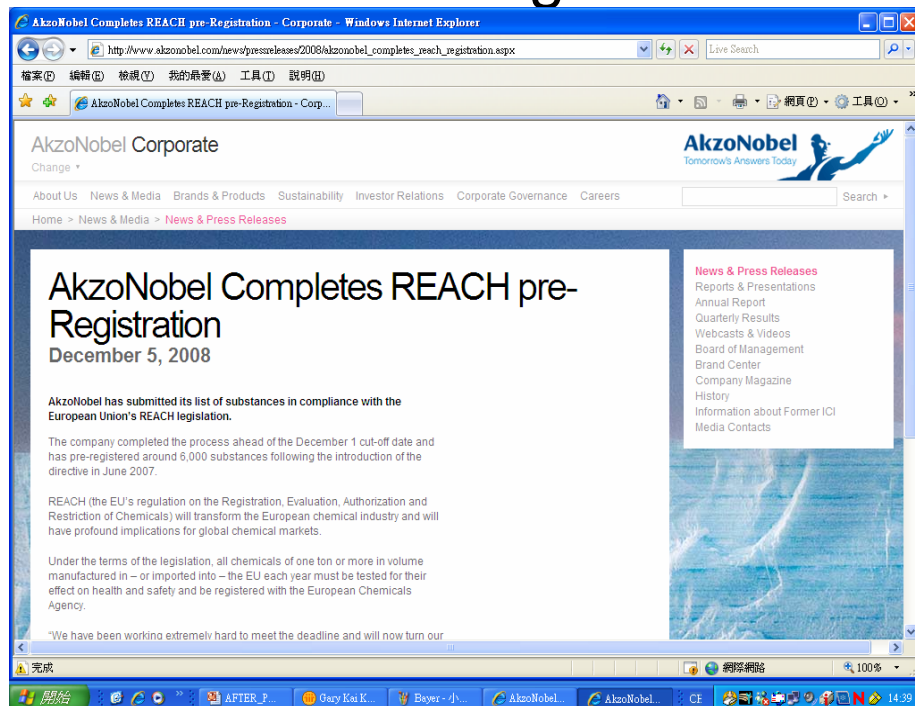
- Example of companies accomplished pre-registrations of REACH
 - **BASF** submits 40,000 pre-registrations
 - **AkzoNobel** (supply of paints, coatings and specialty chemicals) completes REACH pre-registration : submits 6,000 substances
 - **Rhodia** (production of specialty chemicals) announced that it has completed the pre-registration of 736 chemical substances
 - **Arkema** (supply of vinyl products, industrial chemicals and performance chemicals) achieves pre-registration of 470 substances

Source : Chemie.DE Information Service

Status of Pre-registration



Status of Pre-registration



Status of Pre-registration



Status of Pre-registration

- A list of pre-registered substances published on 19 December 2009
- The list contains about 150,000 substances
- pre-registered by 65,000 companies
- ECHA will perform the screening process and update the list

– Source : ECHA



Enforcement of REACH

- REACH (Titles XIII and XIV) requires each Member State to appoint a Competent Authority (CA) and maintain an appropriate control system with respect to enforcement
- Member States are required to have an enforcement regime in place by 1 December 2008
- Provides for effective, proportionate and dissuasive penalties for non-compliance
- Provides results of inspections, monitoring and penalties that are to be reported to the European Commission by 1 June 2010, and after that every five years



Enforcement of REACH

- Establishment of a “Forum for Exchange of Information on Enforcement”
- Coordinate enforcement projects and joint inspections
- Develop working methods and tools for inspectors
- Identify enforcement strategies and develop an electronic information exchange procedure



Status of Enforcement of REACH

- A Forum for Exchange of Information on Enforcement Meeting was held in Helsinki on 2 - 4 December 08
- Not all Member States had managed to finalise their penalty legislations by 1 December 2008
- The Forum adopted a general enforcement strategy which could be used by the Member States as a framework for developing their national strategies - document to be published later on ECHA website
- The Forum also decided to develop minimum criteria for REACH inspections




Status of Enforcement of REACH - UK

- UK REACH enforcement regime has been developed
- Department for Environment, Food and Rural Affairs (Defra) has the policy lead on REACH and has developed the enforcement arrangements
- The enforcement regime for REACH has been implemented by the **REACH Enforcement Regulations 2008**



Status of Enforcement of REACH - UK

- The Regulations allocate responsibility for REACH enforcement to a number of enforcing authorities and provide them with powers they need
 - the Health and Safety Executive (HSE);
 - the Health and Safety Executive for Northern Ireland (HSENI);
 - the Environment Agency (EA);
 - the Scottish Environment Protection Agency (SEPA);
 - the Northern Ireland Environment Agency (NIEA)
 - the Department of Energy and Climate Change (DECC); and
 - Local Authorities (LAs), as regards health and safety and consumer protection (trading standards).
- The Regulations also require enforcing authorities to cooperate and share information with other bodies connected to REACH enforcement
- Set down the offences and penalties for contraventions of REACH requirements



Next Step : Substance Information Exchange Forum (SIEF)

- Substance Information Exchange Forum (SIEF)
- Formation of SIEF for data sharing and avoidance of unnecessary testing or duplication of studies
- Exchange of information within SIEF facilitated by a co-ordinator
- Eventually to registration of substance



Candidate List of Substances of Very High Concern

- 15 substances identified in the Candidate List of SVHC for authorisation
- Possible legal obligations of the companies
- Obligations are linked to the listed substances on their own, in preparations and in articles



What is SVHC

CMR

- Carcinogenic
- Mutagenic
- Toxic for reproduction

(category 1 and 2)

PBT

- Persistent
- Bioaccumulative
- Toxic

vPvB

- very persistent
- very bioaccumulative



First Candidate List of SVHC

Substance Name
Anthracene
4,4'- Diaminodiphenylmethane
Benzyl butyl phthalate
Bis (2-ethyl(hexyl)phthalate) (DEHP)
Dibutyl phthalate
Cobalt dichloride
Sodium dichromate
Lead hydrogen arsenate
Diarsenic pentaoxide
Triethyl arsenate
Diarsenic trioxide
5-tert-butyl-2,4,6-trinitro-m-xylene (musk xylene)
Hexabromocyclododecane (HBCDD) and all major diastereoisomers identified (α - HBCDD, β -HBCDD, γ - HBCDD)
Alkanes, C10-13, chloro (Short Chain Chlorinated Paraffins)
Bis(tributyltin)oxide



SVHC – Possible Legal Obligations

ARTICLES

- From 28 October 2008, EU & EEA suppliers of articles which contain substances on the Candidate List in a concentration above 0.1% (w/w) must provide sufficient information, available to them, to their customers and on request to a consumer within 45 days of the receipt of this request. This information must ensure safe use of the article and, as a minimum, include the name of the substance.
- From 2011, EU and EEA producers or importers of articles have to notify ECHA if their article contains a substance on the Candidate List. This obligation applies if the substance is present above 0.1% (w/w) and its quantities in the produced/imported articles are above 1 tonne in total per year per company
 - For substances included in the Candidate List before 1 December 2010, the notifications have to be submitted not later than 1 June 2011
 - For substances included in the Candidate List on or after 1 December 2010, the notifications have to be submitted no later than 6 months after the inclusion.



SVHC – Possible Legal Obligations

SUBSTANCES

From 28 October 2008, EU & EEA suppliers of a substance have to provide a safety data sheet to their customers when the substance is on the Candidate List.



SVHC – Possible Legal Obligations

PREPARATIONS

From 28 October 2008, EU and EEA suppliers of a preparation not classified as dangerous according to Directive 1999/45/EC have to provide the recipients, at their request, with a safety data sheet if the preparation contains at least one substance on the Candidate List and its individual concentration is at least 0.1% (w/w) for non gaseous preparations and at least 0.2% by volume for gaseous preparations.



Authorisation

- For substances listed in Annex XIV (SVHC), an authorisation is required for their use and their placing on the market
- First list expected to be released by 1 June 2009
- Applications for authorisations (Article 62)
- Holders of an authorisation shall include the authorisation number on the label (Article 65)
- Downstream users using a substance shall notify the ECHA with 3 months (Article 66)



Restriction

- Inventory of restrictions (1 June 2009)
- Annex XVII
- Regulate Community-wide conditions for manufacture, placing on the market or use of certain substances where there is an unacceptable risk to human or the environment or prohibit any of these activities



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Thank You!