

REACH

OVERVIEW AND UPDATE

A business perspective

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Structure of presentation

- ❑ Overview of the REACH strategy
- ❑ Basics of REACH requirements and implications for you
- ❑ EU Developments and help since June 2007
- ❑ Challenges for business

Overview of the REACH strategy

What were the problems for which REACH is the answer?

- ❑ Concerns from users and environmentalists about 'safety' of chemicals
- ❑ Lack of confidence in information about chemicals
- ❑ EU assessment schemes too slow and cumbersome
- ❑ Users unable to properly assess and manage risks

EU hopes from REACH

- ❑ Shift obligation for chemicals from governments to business.
- ❑ More information on health and environment effects to reassure users
- ❑ Stimulate introduction of new (and safer) chemicals to the market
- ❑ Europe will be benchmark assurance scheme for chemicals

What could be the effects of REACH

- ❑ Useful chemicals could be removed from the market.
- ❑ Inconsistencies of advice and approaches from Member States
- ❑ Delays and public conflicts by groups appealing decisions particularly for authorisations etc
- ❑ Restructuring of EU chemicals market
- ❑ Chemicals used abroad and final products introduced to EU eg painted furniture. coated steel, dyed textiles
- ❑ Loss of basic knowledge on technology, processes and toxicology shift to admin of REACH



No need for panic because

- ❑ Testing for classification labelling and packaging needed since 1967
- ❑ Safety Data Sheets for work use needed since 1991
- ❑ Risk assessment of use of chemicals needed by downstream users since 2001
- ❑ Safety for consumer products needed since 1987 ish
- ❑ REACH has been the biggest and longest consultation exercise in EU legislative history (first mooted 1998)
- ❑ Registration and paying a fee should be the only additional requirement as the information to support the above should be available!!!!!!!!!!!!
- ❑ Most industries are in the same boat

Basics of REACH requirements and implications for you

The main industry focus in REACH

☐ Manufacturer/importer of chemicals

- register substances with information package at the ECHA in Helsinki
- direct recipients/users in appropriate risk management measures (RMM) for any particular use of the substance
- respond to other players on other aspects of REACH.

☐ Recipient/user of chemicals

- use substances in manner described by **suppliers**, using RMM prescribed
- feedback to supplier experience in use.
- may need to supply risk assessment and RMM to the ECHA if they do not wish their supplier to know about how they use the supplied chemicals.

The main elements of REACH affecting you

- ❑ Formal Registration of chemicals by EU mfgrs / importers to EU Agency.
 - (Non EU firms can establish registration base in EU - only representative)
- ❑ Submission of dossier - including
 - details of hazards
 - risks and
 - controls for all registered uses
- ❑ Scheme for authorisation and restriction for problem substances

Preregistration needs (June 2008 – 31 Nov 2008)

- Data gathering and sharing
- Working with Agency, users and competitors
- Expertise
- Investments and fees
- Pre registration leads to formation of substance information exchange fora (sief)
- Full registration progressively introduced by 2018

NO REGISTRATION NO MARKET

Full registration requires

- ❑ **Technical dossier** including:
 - Description of uses / quantities etc
 - Assessment of risks and identification of precautions for uses
 - Identification of data gaps and plans for providing missing data

- ❑ **Agency fee**

Co-operate to reach REACH!

- ❑ M/I and DU - start talking to each other today!
- ❑ Screen available data on substances and prepare data sharing
- ❑ New: Start to prepare for exposure scenarios
 - What are your uses of dangerous substances?
 - How can these best be expressed in (broad) exposure scenarios?
- ❑ Co-operate within business associations/consortia
- ❑ Use the flexibility in the interpretation and review of the legislation
 - *Industry gets the obligation, but also the chance to shape dossiers*

EU Developments and help since June 2007

Proposal for GHS introduced

- ❑ Provides international basis to define and classify chemicals according to hazards
- ❑ Communicate this information via labels and safety data sheets.
- ❑ Target audiences - consumers, workers, transport workers, emergency responders
- ❑ There are differences in classification between current EU and GHS. (much detail)
- ❑ Will go through EU codecision procedure

The timelines for REACH and GHS

- ❑ 1 June 2007: REACH enters into force
- ❑ 1 June 2007: European Chemicals Agency becomes operational.
- ❑ 1 June 2008: EU systems fees and charges apply
- ❑ 1 June 2008 to 1 December 2008: Pre-registration of 'phase-in' substances.
- ❑ 30 November 2010: Registration deadline
 - substances 1000 +tn/yr
 - Substances very high concern (SVHC) ie carcinogens, mutagens and substances toxic to reproduction (CMR category 1 and 2) 1+ tn/year
 - substances classified very toxic to aquatic organisms (R50/53)100+ tn/yr
- ❑ 1 Dec 2010: substances classified in accordance with GHS
- ❑ 31 May 2013: Registration deadline substances 100 + tn/yr.
- ❑ 1 June 2015: mixtures classified in accordance with GHS
- ❑ 31 May 2018: Registration deadline substances 1 + tn/yr
- ❑ Voluntary registration prior to deadlines is possible. **Registration dossiers can be submitted from 1 June 2008.**
- ❑ **New substances** need to be registered before they are placed on the market. Their **registration** will start on **1 June 2008.**

European Chemicals Agency ECHA

- ❑ ECHA Europe's Central Agency for the chemicals regulation
 - One of the few agencies that can take legally binding decisions
 - Started 1 June 2007

- ❑ ECHA in future:

- Staff:

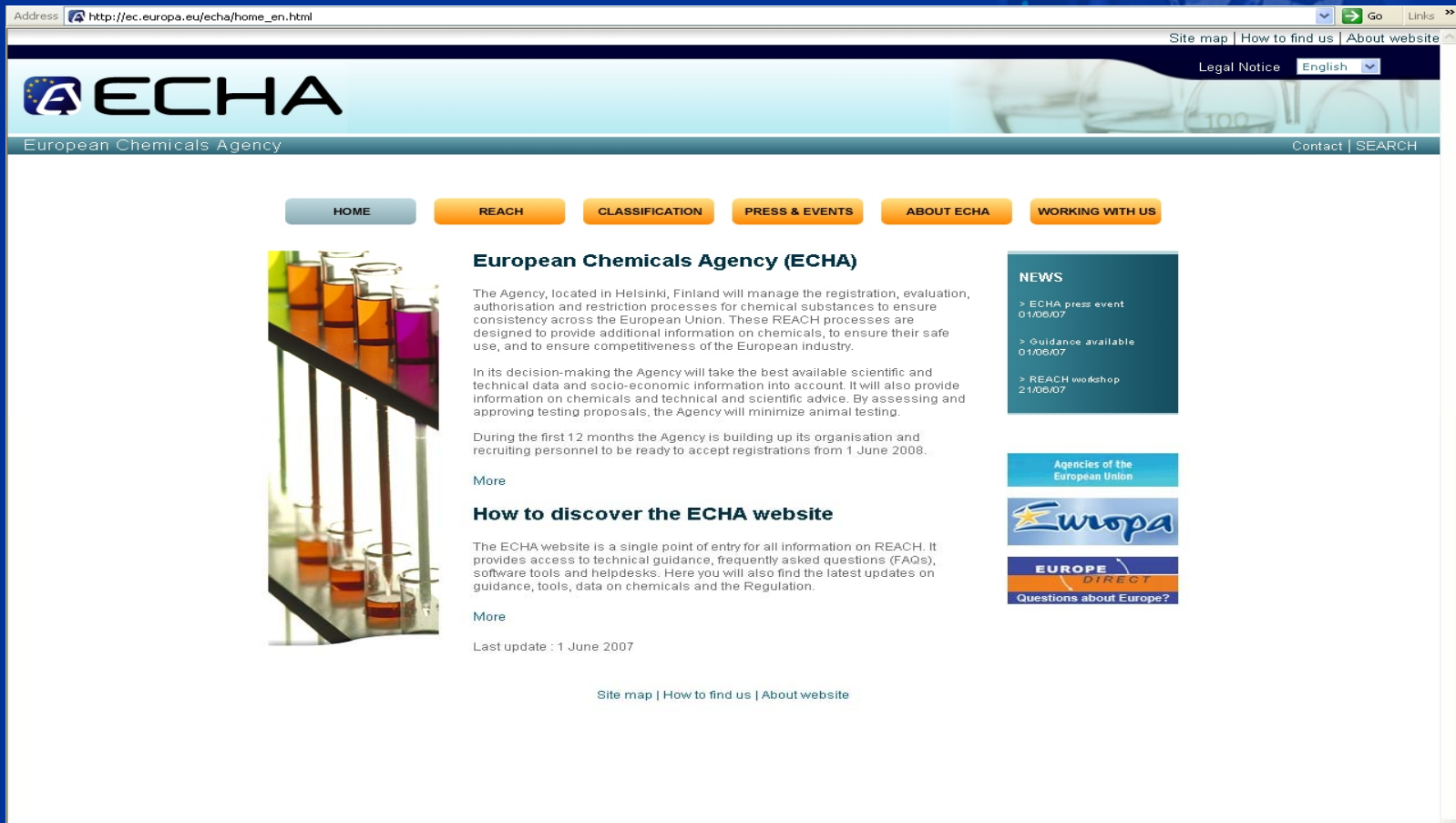
- end 2007: 100
 - 2008: 200
 - 2010: 450

- Budget:

- 2007: € 15 m/a
 - **in future around € 90 m/a - and business is paying**



The ECHA website: <http://echa.europa.eu>



The screenshot shows the ECHA website homepage. At the top, there is a navigation bar with the ECHA logo and the text "European Chemicals Agency". Below this is a horizontal menu with buttons for "HOME", "REACH", "CLASSIFICATION", "PRESS & EVENTS", "ABOUT ECHA", and "WORKING WITH US". The main content area features a large image of test tubes on the left and text on the right. The text describes the Agency's role in managing REACH processes and provides information on how to discover the website. A "NEWS" section on the right lists recent events and guidance. At the bottom, there are links for "Site map", "How to find us", and "About website".

Address http://ec.europa.eu/echa/home_en.html Go Links

Site map | How to find us | About website

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ECHA
European Chemicals Agency

Contact | SEARCH

HOME REACH CLASSIFICATION PRESS & EVENTS ABOUT ECHA WORKING WITH US

European Chemicals Agency (ECHA)

The Agency, located in Helsinki, Finland will manage the registration, evaluation, authorisation and restriction processes for chemical substances to ensure consistency across the European Union. These REACH processes are designed to provide additional information on chemicals, to ensure their safe use, and to ensure competitiveness of the European industry.

In its decision-making the Agency will take the best available scientific and technical data and socio-economic information into account. It will also provide information on chemicals and technical and scientific advice. By assessing and approving testing proposals, the Agency will minimize animal testing.

During the first 12 months the Agency is building up its organisation and recruiting personnel to be ready to accept registrations from 1 June 2008.

More

How to discover the ECHA website

The ECHA website is a single point of entry for all information on REACH. It provides access to technical guidance, frequently asked questions (FAQs), software tools and helpdesks. Here you will also find the latest updates on guidance, tools, data on chemicals and the Regulation.

More

Last update : 1 June 2007

Site map | How to find us | About website

NEWS

- > ECHA press event
01/06/07
- > Guidance available
01/06/07
- > REACH workshop
21/06/07

Agencies of the European Union

Europa

EUROPE DIRECT
Questions about Europe?

Some of what business is getting for the money!

ECHA - organisation (1)

Body	Role	Starts
Executive Director	Legal representative of Agency, reports to the Management Board.	Nomination foreseen in autumn 2007
Management Board	Governing body: nominations, financial planning, annual reports & strategic documents.	First meeting 27-29 June 2007
Secretariat	Supports Committees and Forum; responsible for registration, evaluation, guidance, IT infrastructure and helpdesk.	From summer 2007
Board of Appeal	Considers appeals against Agency decisions	When the 1 st appeal is submitted

Some more of what business is getting for the money!

ECHA - organisation (2)

Body	Role	Starts
Member State Committee	Opinions on <ul style="list-style-type: none"> •draft evaluation decisions •proposals for identification of SVHC 	From 2008
Risk Assessment Committee	Opinions on <ul style="list-style-type: none"> •applications for authorisation •proposals for restrictions •harmonised classfcn and labelling. 	From 2008
Committee for Socio-economic Analysis	Opinions on <ul style="list-style-type: none"> •applications for authorisation •proposals for restrictions •socio-economic impact of possible legislative action. 	From 2008
Forum	Coordinates network of Member States' competent authorities responsible for enforcement	From 2008

and more of what business is getting for the money!

Helpdesks under REACH

- ❑ **Member States helpdesks - most established**
 - Individual advice on obligations under REACH
- ❑ **Agency helpdesk for registration - signpost at present**
including helpdesk on IUCLID5
 - General advice on registering according to Article 77 (2) h
 - Information on dossiers
- ❑ **Agency support for national helpdesks**
 - Coordination of network of helpdesks
- ❑ **Industry helpdesks**
 - Complementary function, industry-specific advice

IT tools for REACH

- ❑ REACH IT: IT Infrastructure for the Agency and Member States, Essential parts available but full development by June 2008
 - Submission of pre-registration and registration
 - Data management for the Agency and Member States

- ❑ IUCLID 5: Data-base for industry, available now
 - Interface with REACH -IT, to be able to submit registration files to Agency
 - Interface with other IT-systems developed by industry or their partners (e.g. Safety Data Sheet tools, priority setting tools, Life Cycle Assessment (LCA) tools, etc.) Interface with REACH-IT
 - Satisfy international dimension(OECD ICCA, US-EPA, etc)

Information on ECHA website from RIP projects etc

- ❑ guidance documents on registration, PPORD, intermediates, polymers, substance identification, IUCLID, evaluation, preparing Annex XV dossiers for harmonised C&L, identification of SVHC, restrictions proposals - reflecting work on
 - *RIP 3.1 – TGD on preparing a registration dossier / Overall Guidance some already on website*
 - *RIP 3.10 - TGD for characterisation and checking of Substance Identity*
 - *RIP 4.1/4.2 - TGD on dossier and substance evaluation*
 - *RIP 4.4 - TGD on Annex XV dossier*
- ❑ the Navigator - an IT-tool to help industry determine its obligations under REACH .
- ❑ Further guidance documents will be uploaded on the website as soon as they are finalised.

State of other RIP projects

□ *Near completion*

- *RIP 3.5-2 – TGD on Downstream users requirements*
- *RIP 3.8 - TGD on requirements for substances in articles*

□ *Still in progress*

- *RIP 3.2-2 – TGD on preparing the Chemical Safety Report – second phase*
- *RIP-3.3-2 – TGD on Information requirements – second phase*
- *RIP-3.4 – TGD on Data-sharing*
- *RIP 3.7 - TGD on preparation of an application for authorisation*
- *RIP 4.3/4.5 - Guidance document on inclusion of substances in Annex XIV and guidance document on Priority setting for evaluation*

□ *Longer term*

- *RIP 3.6 – TGD on the draft Regulation on Classification and Labelling implementing the Globally Harmonised System in the EU` - . Several Working groups are expected to be established.*
- *RIP-3.9 – Guidance on carrying out a Socio-economic analysis (SEA) March 2008*

Challenges for business

The law is being interpreted, reviewed and amended

- ❑ Annex I
- ❑ Annex IV (exempt substances)
- ❑ Annex V (groups of exempt subs
- ❑ Substances in articles
- ❑ Annex XI and XIII

- ❑ are they going to shift the goalposts
- ❑ Needs further monitoring for threats and opportunities



Company resources for communications

- ❑ WITH EU INSTITUTIONS
- ❑ EU LEVEL CONSORTIA
- ❑ INTER SECTOR
- ❑ INTER COMPANY (manufacturers/importers)
- ❑ INTER COMPANY (downstream users)
- ❑ INTERNALLY - PR, legal, technical, marketing functions

Strengths and weaknesses for business

weaknesses

- ❑ business has to take strategic decisions when law and duties are still unclear
- ❑ costs unknown
- ❑ growth industry in REACH intermediaries
- ❑ coming at a time when other major changes in global manufacturing

strengths

- ❑ business is planning for REACH
- ❑ good guidance is being developed
- ❑ considerable support networks are developing

GRASP THE NETTLE

- ❑ REACH IS A GLOBAL BUSINESS ISSUE
- ❑ REACH WILL DRIVE MAJOR CHANGE IN THE WAY CHEMICAL BUSINESS IS ORGANISED
- ❑ REACH A MAJOR THREAT TO SUPPLY CHAIN CONTINUITY
- ❑ YOUR DECISIONS AND INFORMATION WILL BE UNDER INTENSE SCRUTINY
- ❑ CLEAR AND DECISIVE LEADERSHIP AND MANAGEMENT NEEDED

Thank you

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