

REACH, background information & state of play

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etui.

- How does REACH work ?
- What is the current situation on REACH ?
- Conclusions

REACH= Registration, Evaluation, Authorisation of Chemicals

White Paper

OBJECTIVES = Sustainable Development

- Achieve a high level of protection for human health and the environment
- Promote the efficient functioning of the EU internal market and enhance the competitiveness of the EU chemical industry

Entry into force

Feb, 2001

June, 2007

- **Shifting the burden of proof:** Manufacturers of chemicals will have to prove that their substances can be used safely
- **No data = No market**
Manufacturers will have to register their substances and provide data if they want them to stay/be on the market

REACH in a nutshell

- **Registration:** Manufacturers and importers of chemicals > 1 tpa are required to register their substances to demonstrate they can be used safely
- **Evaluation** of some substances by Member States / European Chemicals Agency
- **Authorisation** only for substances of very high concern
- **Restrictions** when risks are unacceptable

Registration

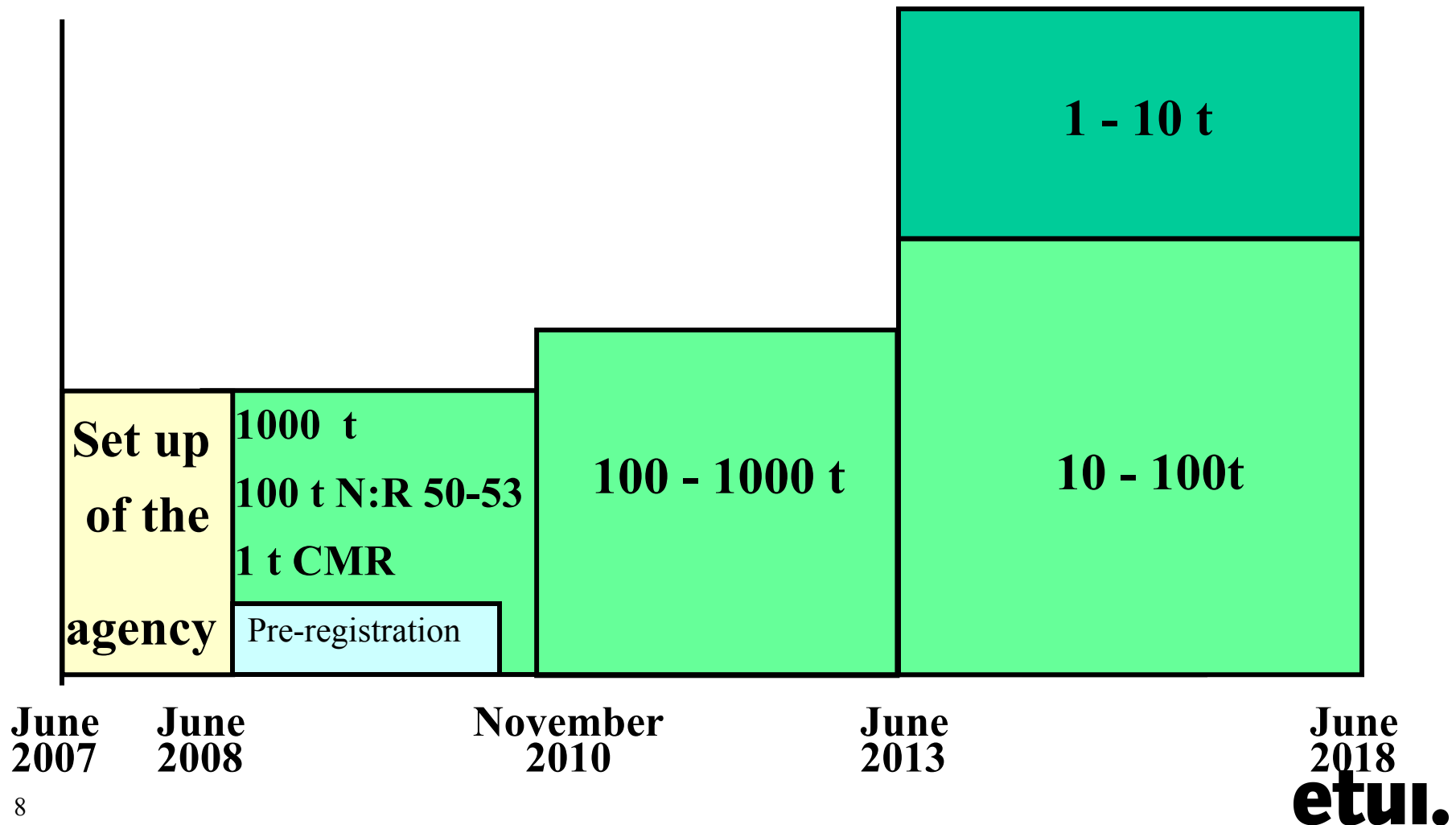
- Chemicals > 1 tonne/year per manufacturer (~ 30 000 existing substances + all new substances to be put on the EU market)
- Manufacturers/Importers collect and submit data through a registration dossier:
 - Technical dossier (>1t/y)
 - Chemical Safety Report (> 10t/y)
- European Chemicals Agency (ECHA) will receive the registration dossiers and manage the database

Data required depend on production volume

Data Sharing for producers of same substance

- Avoidance of unnecessary animal testing + saving of cost
- Sharing of animal test data is mandatory - of other data is voluntary
- Information > 12 years – freely available on request
- For new substances, Agency enables contact with any previous registrants and costs are shared.
- For existing substances (phase-in) :
 - Pre-registration: enables contact and overview about available information
 - Substance information Exchange Forum (SIEF): to agree on sharing of existing data and costs to agree who performs any new tests
- If registrant refuses to share → sanctions

Timeline for registration of 30 000 existing substances



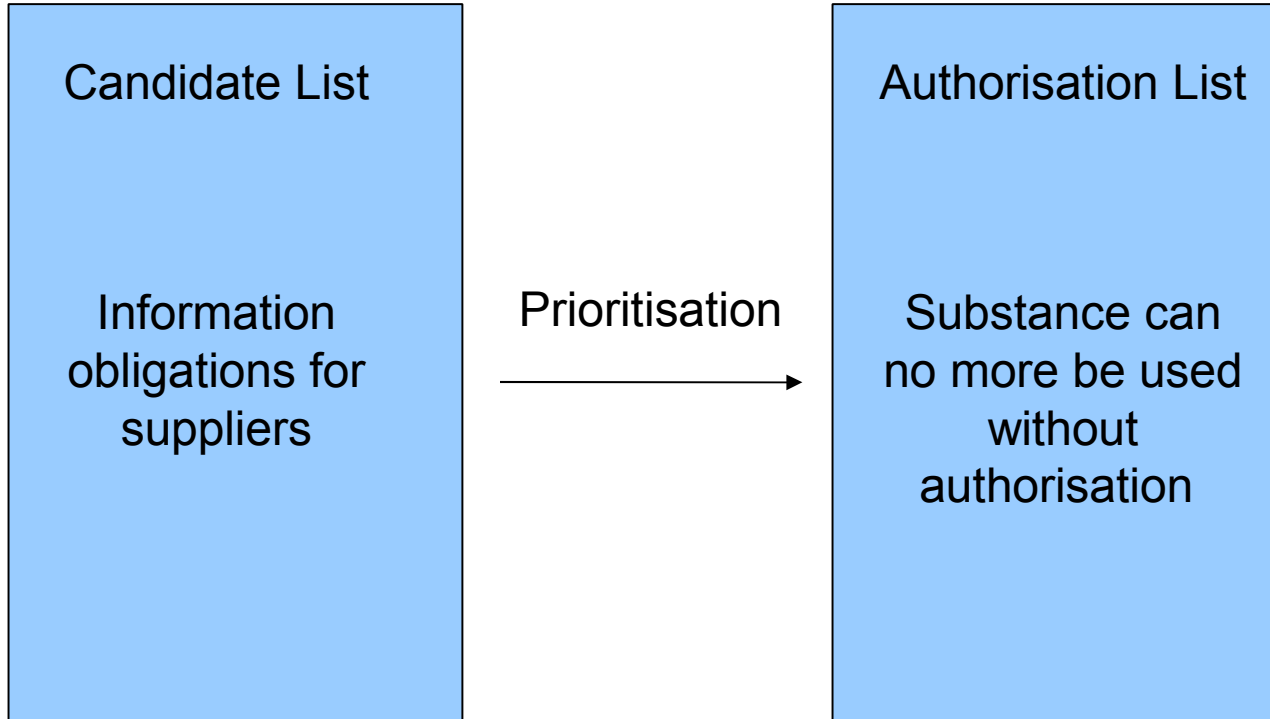
- 2 types of evaluation:
 - Dossier evaluation (animal testing/compliance)
 - Substance evaluation when a substance may present a risk to human health or the environment
- Results of evaluation:
 - No further action
 - Industry can be asked for more info
 - Substance needs to be regulated further
Eg: authorisation or restriction procedures

Authorisation

- For each use of substances of very high concern: PBTs, vPvBs, CMRs (1&2), equivalent concerns
- Authorisation is granted by the Commission if
 - **Route 1** : Industry can prove the risk is adequately controlled
 - **Route 2** : Socio-economic benefits > risks & No suitable alternatives are available
- No Authorisation granted if:
 - Use is not considered to be adequately controlled
 - Benefits are smaller compared to risks
 - Suitable substitutes are available (for route 2 only)
- All authorisations will be reviewed (case-by-case)

Authorisation procedure

Substances of very high concern:
PBTs, vPvBs, CMRs (1&2), equivalent concerns



Aim: safety net when risks are unacceptable

- Manufacture, use and placing on the market of substances on their own, in preparations or in articles
- Proposals for restrictions are prepared by Member States or ECHA on behalf of the European Commission
- ECHA gives opinion on each proposal
- Interested parties can comment (public consultation)
- European Commission takes final decision
- REACH takes over existing restrictions from previous EU legislation (annex XVII)

REACH & Information through the supply chain

Communication down the supply chain

- Manufacturers and importers have the duty to communicate to their customers how the substance can be used in a safe way (Risk Management Measures in an annex to the SDS)
- Each actor in the supply chain shall pass on the information received to the next actor down the supply chain

Communication up the supply chain

- A downstream user as the right to make its use known to the supplier
- A downstream user has the duty to inform his supplier about:
 - Inappropriateness of risk management received in SDS
 - New information on the hazardous properties of the substance

REACH and Classification & Labelling

- Criteria for C&L laid down in Classification, Labelling and Packaging (CLP) Regulation adopted in 2008 to implement Globally Harmonised System
- Industry to self-classify all substances or mixtures placed on market; some substances with EU harmonised classification (Annex VI of CLP Regulation)
- REACH: in addition - industry to notify ECHA of all substances classified as hazardous by January 2011 (regardless of production volume)
- ECHA to maintain an inventory publicly available
- Industry to make all efforts to harmonise the C&L of substances, where there are differences
- Harmonisation by authorities required only for CMRs (cats 1,2 and 3) and respiratory sensitisers

European Chemicals Agency (ECHA)

- ECHA's main task is to manage the technical, scientific and administrative aspects of the REACH regulation
- ECHA is based in Helsinki, Finland
- 1st June 2008 ECHA & REACH entry into operation
- 1st January 2010, ECHA has a staff of ~ 350 people (up to 600 people foreseen in 2011/2012)

How is ECHA organised ?

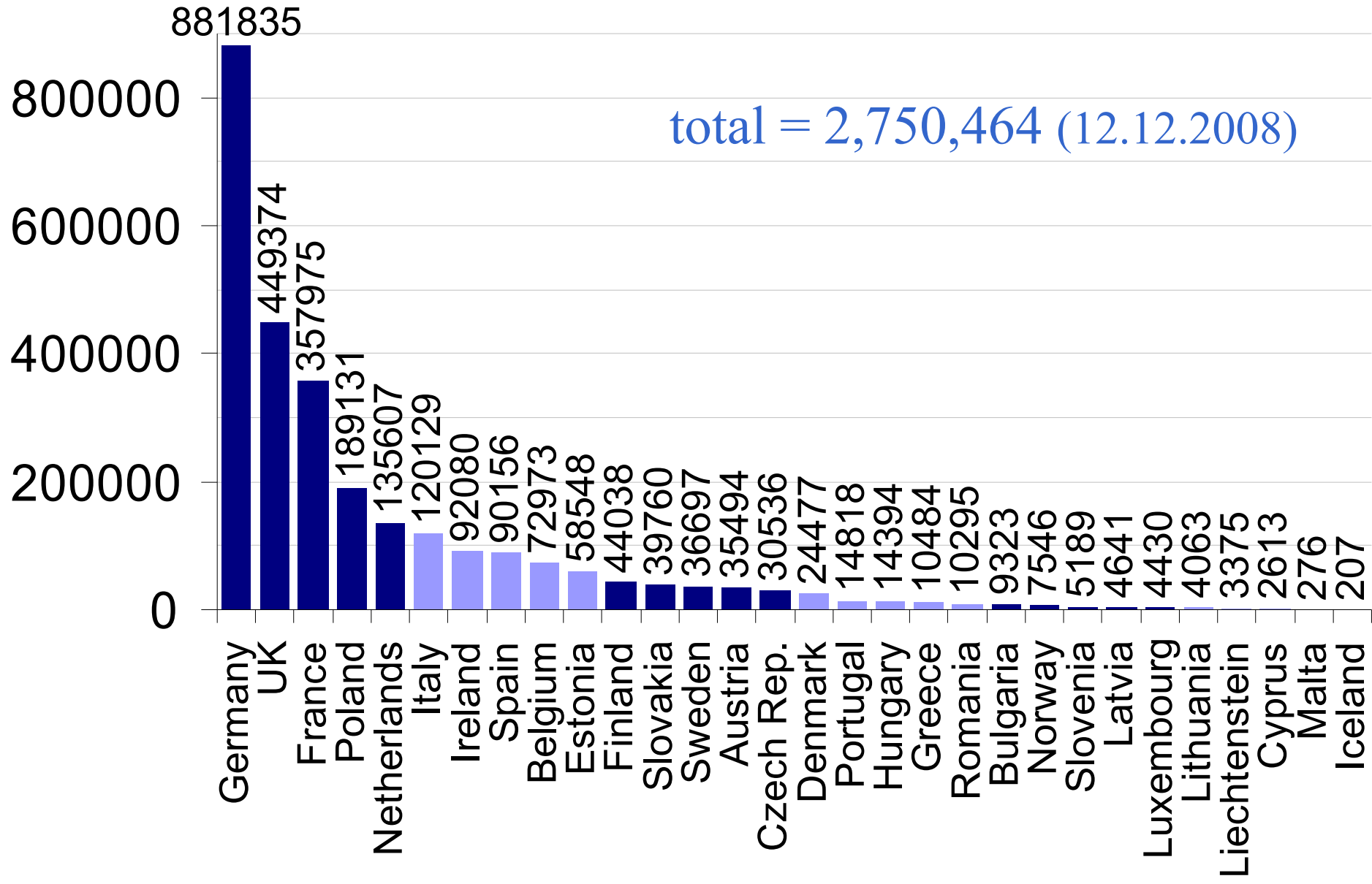
- Executive Director (Mr Geert Dancet)
- Management Board (35 members)
 - One representative by Member State (27 members)
 - 2 independent members representing the EU Parliament
 - 3 members representing the European Commission
 - 3 members representing the interested parties (Industry, Envi NGO and Trade Unions (=ETUC))
- Secretariat : provides support to 3 the Committees and Forum
- Risk Assessment Cttee (authorisations and restrictions)
- Socio-Economic Analysis Cttee(authorisations and restrictions)
- Member State Cttee (evaluation, C&L and identification of SVHC)
- Forum (enforcement)
- Board of Appeal: decides on appeals against decisions taken by the Agency

What is the current situation on REACH ?

Pre-registration

- 6 months of pre-registration from 1st June to 1st December 2008
- More than 65 000 companies from all 27 MS + EEA
- More than 2 700 000 pre-registrations received
- ~140 000 different substances pre-registered
- Thousands of substances pre-registered by companies with no real intention to register them
- Substance Information Exchange Forum (SIEF) formed for each pre-registered substance with the same identity
- SIEF role is to help companies who intend to register the same substance to share data and costs
- ~ 2200 SIEFs already formed (situation in December 2009)

Pre-registration



Registration

- First registration deadline is 30 November 2010
 - Substances > 1000 t/y
 - Substances toxic or harmful to aquatic organism > 100 t/y
 - CMRs > 1t/year
- ~ 9000 substances expected to be registered by that deadline
- ~ 900 registration dossiers received by ECHA (situation end 2009)
 - 1/3 existing substances (phase-in)
 - 2/3 new substances (non phase-in)
- Non-confidential registration information already available on ECHA's website for some substances

See: <http://apps.echa.europa.eu/registered/registered-sub.aspx>

- Information on registered substances will be progressively uploaded on ECHA's website

Evaluation

- Compliance check has started for a few substances
- ECHA agreed on first testing proposals at the end of 2009

Authorisation

- 29 Substances of Very High Concern (SVHC) on the Candidate list (situation Jan 2010) out of 1500-2000 possibly on the EU market
- EU court case T-1/10 R postponed the publication of acrylamide as SVHC on the Candidate list
- 7 SVHC recommended by ECHA as priority for inclusion in the Authorisation list (June 2009) but European Commission decision still pending
- Suppliers of these substances will have to apply for authorisation around spring 2010 & first authorisation decisions expected in 2013
- ECHA capacity: 10-15 substances/year

Restriction

- Restriction title of REACH entered into force on 1st June 2009
- First restriction proposals are expected in 2010
- ECHA capacity : ~ 5 substances/year

Classification & Labelling

- Deadline for companies to submit the classification of their substances is January 2011
- millions C&L notifications expected by ECHA
- Publication of the C&L Inventory by ECHA around mid-2011
- ~ 90 proposals/year expected for harmonised classification
(annex VI of CLP regulation planned to be updated once per year)

Conclusions

- REACH is the largest legislative project adopted by the EU in recent years
- REACH implementation has started
- REACH will ensure
 - High level of protection (workers, consumers & envir.)
 - Burden of proof on those creating risks
 - Improved knowledge
 - Improved innovation
 - Substitution of dangerous substances
 - Better consumer confidence

Thank you, further info on:

<http://www.etuc.org> > Our activities > REACH

<http://hesa.etui.org> > Dossiers > Chemicals

<http://echa.europa.eu>