MR-REACH. Reglamento REACH. Adaptación de la industria y la cadena de suministro.

LA AGENCIA EUROPEA DE SUSTANCIAS Y PREPARADOS QUÍMICOS Y EL REGLAMENTO REACH

Geert Dancet
Director Ejecutivo
Agencia Europea de Sustancias y Preparados Químicos (ECHA)

Congreso Nacional del Medio Ambiente, Cumbre del Desarrollo Sostenible 5 December 2008, Madrid

Speech by

Geert Dancet, Executive Director

European Chemicals Agency

What is REACH?

- REACH is the Regulation for **R**egistration, **E**valuation, **A**uthorization and Restriction of **Ch**emicals
  - Regulation (EC) No 1907/2006 of the European Parliament and of the Council
  - Entry into force: 1st June 2007
- Entry into operation: 1st June 2008

ECHA - Overview

http://echa.europa.eu

Mission of ECHA

Make REACH work

- **Manage REACH tasks** by carrying out or co-ordinating activities **to ensure a consistent implementation** at EU level
- **Provide** Member States and the EU institutions with the best possible **scientific advice** on questions related to the safety and the socio-economic aspects of the use of chemicals
- **Ensure a credible decision-making process**, using the best possible scientific, technical and regulatory capacities and by working independently in an efficient, transparent and consistent manner

Achievements so far (1/3)

1. **ECHA helpdesk** operational since 18 months
2. **Helpdesk network** helps harmonising advice
3. **Guidance** is on ECHA's website **– a one stop shop**
4. **Committees & Forum** – fully operational
5. **Chemical "*acquis*"** taken over from COM & MS
6. **Recruiting** (2 > 220 in 18 months) and **training** staff
7. **Procedures (SOP)** for key processes **in use**
8. **IT tools** (IUCLID 5, REACH-IT) operational

Achievements so far (2/3)

9. **Stakeholder** partner organisations identified/invited as observers

   First Stakeholders Day organised on October 10th, 2008

10. **National trainers trained** (3 training sessions)
11. **First "candidate list"** published at the end of October 2008
12. **Registrations (169), PPORD notifications (454), inquiries (649)** received and managed by December 1st, 2008

Achievements so far (3/3)

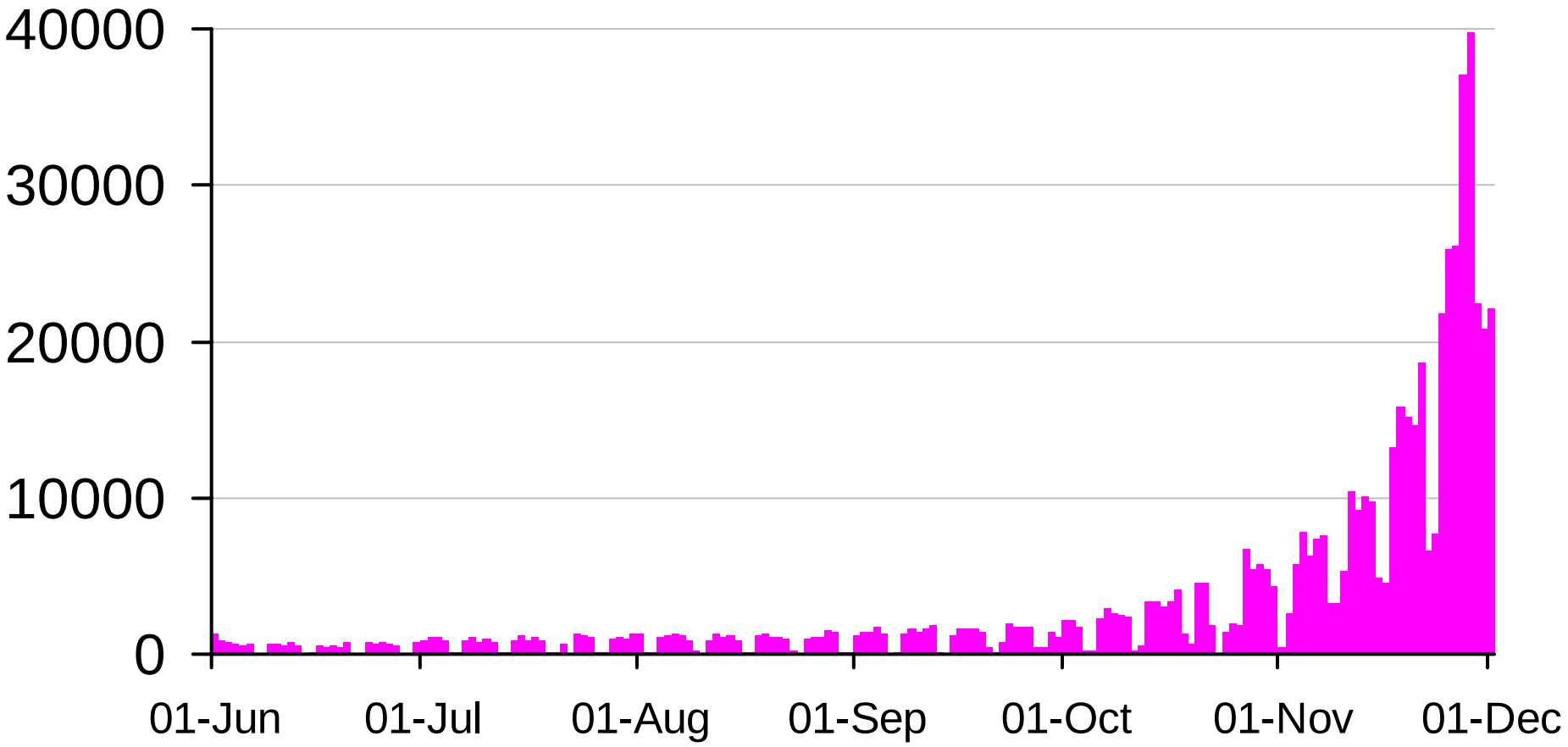
Pre-registrations:

At the end of the pre-registration period:

- more than 65,000 Companies from all 27 MS + EAA
- number of sign-ups was increasing
  - 800 per week in September
  - 1500 per week in October
  - 1st week of November 3500 per week
  - 2nd week of November 5000 per week
  - Last 2 weeks of pre-registration 30.000
- more than 2,200,000 pre-registrations received
  - more than 100,000 different substances pre-registered
- intermediate list (almost 50,000 substances) published on 7 October 2008 and updated on 6 November 2008. Final list: 1 January 2009.

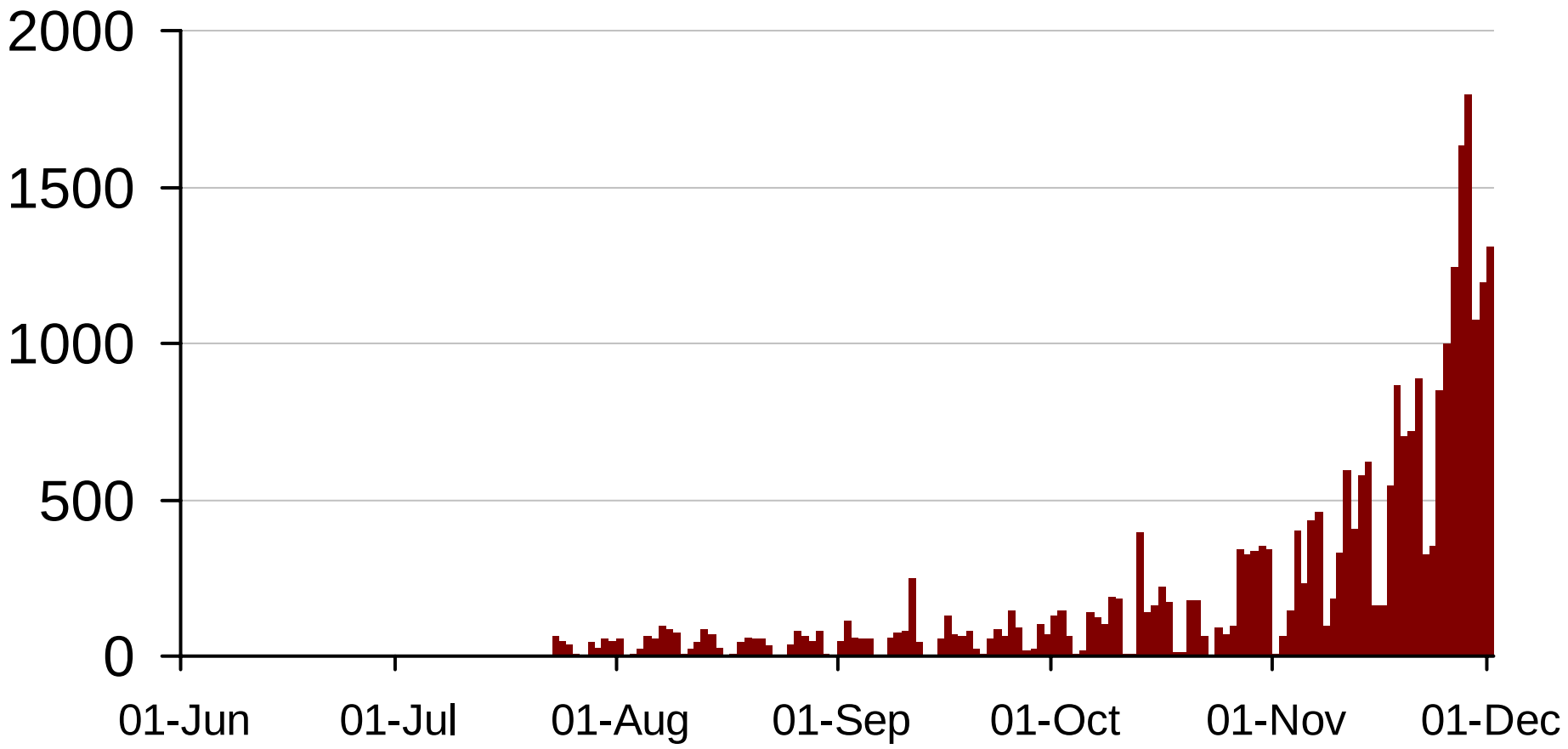
Pre-registration conclusions

- in the last weeks of pre-registration, ECHA received a very high number of manual pre-registrations



Pre-registration conclusions

- in the last weeks of pre-registration, ECHA received a very high number of bulk pre-registration files



Challenges and work for ECHA (2/5)

1. Prepare for the first registration deadline

- Up to 20 000 registration dossiers expected to arrive in 2010
- Deadlines for dealing with testing proposals in registration dossiers are very challenging (1 December 2012)
- Well established procedures and trained staff will be crucial
- CSA/CSR tool to be rolled out by the end of 2009

Challenges and work for ECHA (3/5)

2. Take next steps on authorisation and restriction processes

- Make a credible start on the authorisation procedure and recommend the first SVHC substances for authorisation to COM
- Carry out a regular update of SVHC candidate list
- Prepare for first opinions after the entry into force of restriction process

Challenges and work for ECHA (1/5)

3. Master the technical and scientific tasks of REACH and Classification, Labelling and Packaging (CLP) Regulation:
   - Implement and operate efficient, transparent and secure procedures for all REACH and CLP processes and develop routine
   - Respect the tight deadlines from REACH
   - Ensure the timely availability and development of scientific IT-tools and promote their international acceptance
   - Ensure the availability of adequate and well trained staff
   - Deliver solid opinions from RAC and MSC on harmonised C&L and testing proposals

Challenges and work for ECHA (4/5)

4. Build evaluation capacities

- Dossier evaluation one of the most demanding tasks for ECHA
- Resources need to be built up and workflows established for first registration deadline (2010) for complex high volume substances
- ECHA has to carry out compliance check for at least 5 % of dossiers for each tonnage band

Challenges and work for ECHA (5/5)

5. Build trust with its partners and become key source of information

- ECHA depends on harmonious networks with authorities, industry and other stakeholders
- Core values are Independence, Transparency and the delivery of scientifically and technically sound opinions and decisions
- Make high quality and non confidential information on chemicals easily available to support the aims of REACH

Preparation by Industry

- Substance Information Exchange Forum (SIEF) for co-operation with other registrants: consortia participation, communication, data sharing, joint registration dossier
- Develop core data for registration, minimising new studies by using ‘surrogate data’ & ‘data waivers’ (i.e. use Annex XI of the REACH Regulation)
- Registration dossier preparation by first deadline
- Further studies: proposal for higher-tier animal tests in the registration
- Develop Exposure Scenarios (ESs) for the CSR for all uses in the lifecycle of the substance in the EU

Preparation by Industry (continued)

- Immediate communication obligations for articles containing SVHCs & later notification to ECHA
- Cooperation with Downstream Users (DUs) for supply chain communication obligations
- Revise classification, labelling & Safety Data Sheets (SDSs) for CLP compliance
- Update SDSs with summary CSRs

Potential Bottle-necks

- SIEFs overwhelmed by internal communication & delayed by setting up consortium agreements
- Challenging to get information from DUs to develop ES's
- Lack of regulatory affairs professionals & scientists to prepare registrations & CSR's
- Inadequate capacity of testing facilities for new studies to complete the core data set, also for higher-tier studies
- CSA/CSR tool in development (ECHA priority after successful preregistration)

ECHA's sources of information (1/2)

To receive the latest information about ECHA's work:

- Access to ECHA web site sections "News" and "Press and Events", to know about the Agency and its activities as well as "News Alerts" and "Newsletter" services, available previous subscription

- Download Brochures, Fact sheets and strategic papers issued by the Agency, available on the web site section "Publications"

- Consult the site section "ECHA Chem" to find useful information about chemicals as reported on registration dossiers submitted to the Agency

- Use the possibility to request ECHA's experts to participate as speakers to conferences and the possibility to visit ECHA's premises

ECHA's sources of information (2/2)

To understand REACH and its implementation process (through web site section "REACH"):

- Consult the REACH Regulation, REACH Guidance documents and the Frequently Asked Questions (FAQ) section

- Find quickly what you need to do under REACH by using "The Navigator"

- Keep up-to-date to the state of the play of current pre-registration procedure (web site section "Pre-registration"& "REACH-IT")

- Access and use training tools available

- Subscribe to the news alerts and contact ECHA's Helpdesk in case of problems.

For further information about REACH and ECHA is available on ECHA Website e.g.

- Guidance on REACH
- Dedicated web pages (e.g. “About ECHA”)
- Additional tools: Navigator, CSR-tool (near future), Guidance, Guidance feedback form, Fact sheets, Web Tutorials, Glossary, etc.
- Leaflets, Brochures, Press Services
- Helpdesks