REACH: how to deal with 30,000 chemicals

Challenging boundaries in risk assessment – sharing experiences

EFSA's 10 Year Anniversary

Parma, 7-8 November 2012

Dr Pilar Rodríguez Iglesias
Head of Unit
Committees Secretariat

Driving Legislation for ECHA

- REACH adopted in December 2006
- ECHA established on 1 June 2007
- REACH entry into force June 2008
  - Registration of chemicals [“substances”]
  - Evaluation of selected registered substances
  - Authorisation of (certain) Chemicals
  - Restriction of (certain) Chemicals
- CLP entry into force January 2009
  - Classification, Labelling & Packaging of substances and mixtures

NEW tasks

- Biocides entry into force 22 May 2012
  - entry into operation on 1 September 2013
- PIC entry into force 16 August 2012
  - Prior Informed Consent
  - Entry into operation on 1 March 2014

Philosophy of chemicals management in the EU under REACH & CLP

- Ensure a **high level of protection of human health & environment**
- **Industry takes responsibility for establishing safety** of manufacture & use of chemicals in the whole lifecycle
- Adequate **information on substance properties** for classification of hazards & risk assessment
- Appropriate **alternative methods**
- **Deal with the 'burden of the past'** with a systematic prioritized programme for 'phase-in' substances
- **Risk assessment** either explicitly with formal risk characterisation or implicit in the structure of the legislation
- **Communication of information**, i.e. dissemination by ECHA & to the supply chain
- Deal with **substances requiring regulatory risk management**
- **Stakeholder involvement** & input into decision making

REACH & CLP: roles & responsibilities

- Pre-registration
- Data sharing
- Registration
- Self-Classification

Industry gathers information and ensures responsible and well-informed management of the risks

ECHA
EUROPEAN CHEMICALS AGENCY

MSs

- **Evaluation**
  - **Dossier evaluation**
  - **Substance evaluation**

ECHA and MSCAs control and request for further info

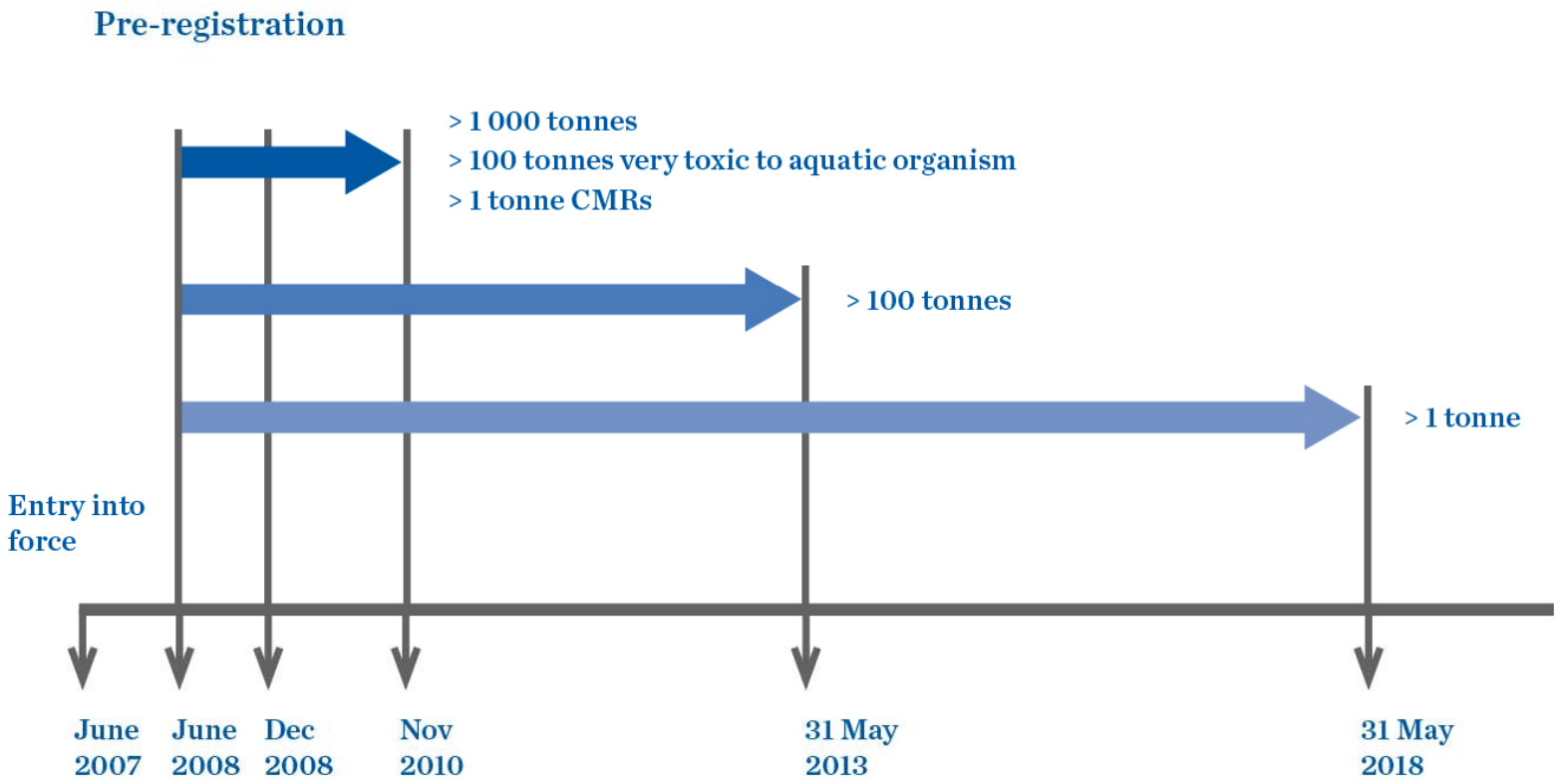
- **Harmonised classification and labelling**
- **Authorisation**
- **Restriction**

COM, with support of ECHA & MSCAs, applies Community-wide risk management measures

REACH: Registration

- **Core of REACH**: EU/EEA manufacturers and importers of chemicals collectively obtain information per substance and use knowledge to ensure safe use
- Registration:
  - IUCLID format technical dossier for substances at 1 t.p.a. submitted using REACH-IT
  - Standard **information linked to tonnage**
  - **Testing Proposals for higher-tier studies** (i.e. at 100 & 1,000 t.p.a.)
  - **Chemical Safety Report** for substances at 10 t.p.a.
  - Transitional arrangements, i.e **'phase in' substances registered in 3 stages**
  - Safety advice to users/customers is provided in extended Safety Data Sheets

Registration deadlines



Key figures from the first deadline

Substances from first deadline:

- ca. 25,000 dossiers
- 4,300 substances:
  - 3400 phase-in substances
  - 900 non-phase-in substances
- Chemical intermediates: 25%
- Large companies: 86%
- Only Representatives: 19%
- Joint Registrations: 94%

→ **Successful completion of this major REACH milestone**

Registration

	Registrations	Disseminated	% Diss	Substances	Disseminated	% Diss
REACH (New registrations)	27 333	25 981	95%	4 639	4 256	92%
NONS* Total	9 962	4 394	44%	5 292	3 407	64%
NONS Updated under REACH	*1 455*	*1 343*	*92%*	*1 291*	*1 205*	*93%*
NONS Claimed but not updated	*3 619*	*3 051*	*84%*	*2 409*	*2 202*	*91%*
NONS Unclaimed	*4 888*	*0*	*0%*	*1 592*	*0*	*0%*

Data as of 6th Sep 2012

	Registrations	Disseminated	% Diss	Substances	Disseminated	% Diss
Total Work Programme Indicators	28 788	27 324	95%	5 930	5 461	92%
REACH (New registrations)	*27 333*	*25 981*	*95%*	*4 639*	*4 256*	*92%*
NONS Updated under REACH	*1 455*	*1 343*	*92%*	*1 291*	*1 205*	*93%*

* NONS = Substances notified under Directive 67/548/EEC - Notification of New Substances

2013 Expectations – Number of substances

Substances relevant for 2013 deadine	**3836**
Of which are 'new' substances to be registered for 2013	*2 968*
Of which were registered for 2010 deadline by a Lead	*868*

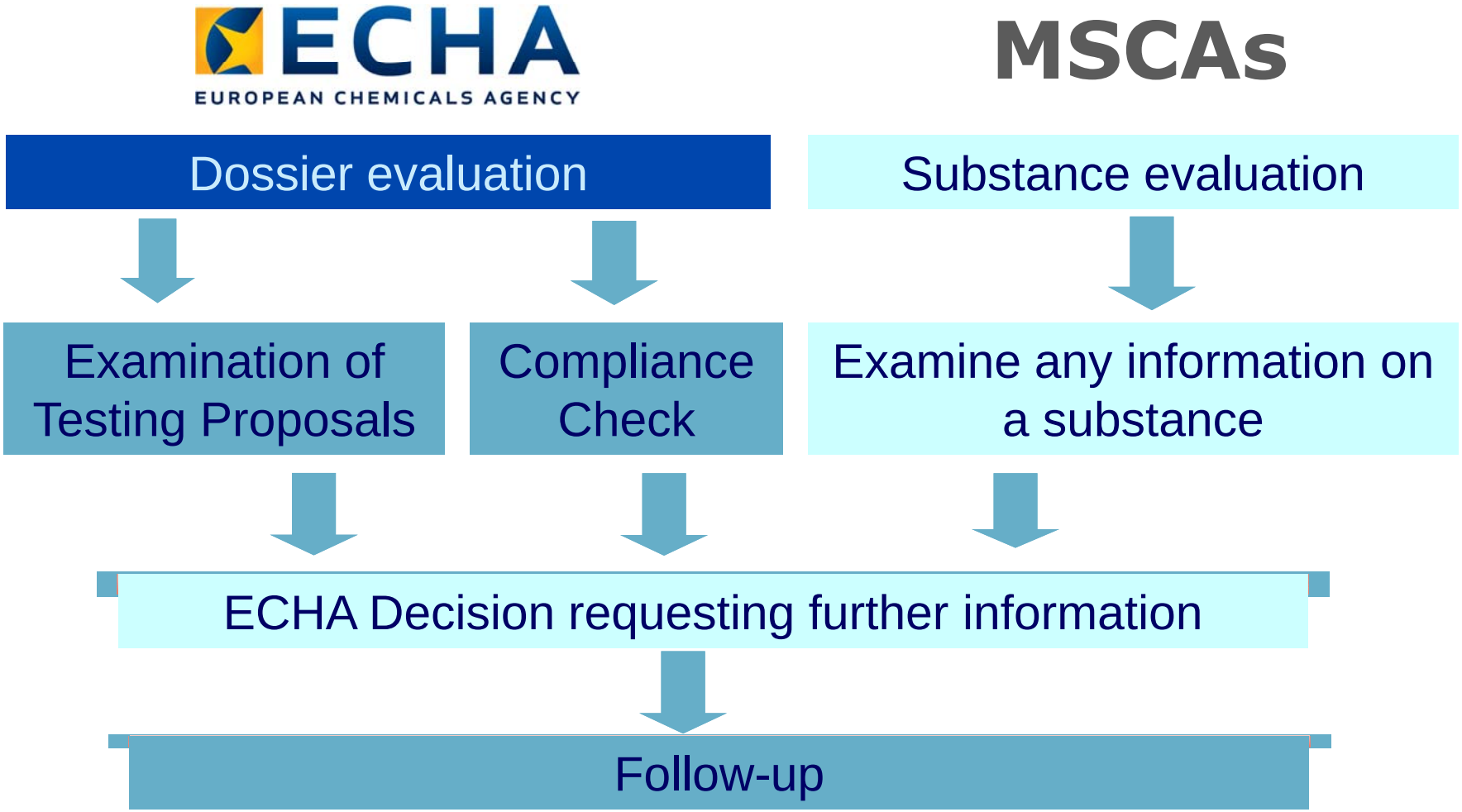
'New' substances to be registered for 2013 deadline	**2 968**
For which a Lead Registrant is known to ECHA	2 215
Of which are already registered by a Lead Registrant	269

'New' substances which are not yet registered and for which no LR nomination has been received by ECHA	**728**

Data as of 27-Sep-12

http://echa.europa.eu/web/guest/information-on-chemicals/registered-substances/identified-substances-for-registration-in-2013

Evaluation



MSCA = Member State Competent Authority

Dossier Evaluation

- **Testing proposal examination**
  - All Testing Proposals from registrants for higher-tier studies have to be evaluated

- **Compliance check**
  - Compliance check allows ECHA to verify that the information meets the data requirements, i.e. although all dossiers have passed a Technical Completeness Check this does not assess quality & adequacy of the registration information
  - Compliance check performed on at least 5% of registration dossiers for each tonnage band

Substance Evaluation

- Substance evaluation is to **clarify potential risk** not identified in the registration (i.e. to get extra hazard &/or exposure data)
- **Member States** undertake the substance evaluation within 12 months
- Potential formal outcome of substance evaluation:
  - Request for further information to clarify risk (a decision) - Can go beyond REACH standard data requirements
  - Risk confirmed or under control → no further information needs to be requested
- First "**Community" Rolling Action Plan** ('CoRAP') adopted in February as a 'rolling' 3-year list for 2012 to 2014
- After obtaining additional necessary information, consider **follow-up actions** under REACH/CPL or other EU regulatory instruments

Evaluation EU wide Risk Management

Risk Management under REACH & CLP: Addressing Chemicals of Concern

- Identification of substances & uses for possible intervention by screening of data from REACH & CLP & other available information (e.g. from third countries or academia)
- Analysis of the most appropriate Risk Management Option, i.e. **RMO analysis**, to ensure that the identified concerns are addressed in an effective, timely and proportionate manner
- Regulatory Risk Management Options:
    - **Harmonised Classification and Labelling**
    - **Authorisation**
    - **Restriction**
    - Measures under **other Community legislation**

Risk management instruments: Classification & Labelling

- Classification and labelling is the first step to define the hazards of chemical substances & mixtures to facilitate safety

- ✓ CLP Regulation (EC) No 1272/2008
  - – Implementation of agreed UN-wide system
- ✓ ECHA role:
  - ✓ Establish & maintain C&L inventory, over 3 million notifications covering over **100,000 substances**
  - ✓ **Harmonised C&L** for CMRs or respiratory sensitizers (or for all hazardous properties for pesticide or biocide active substances)
    - ✓ Proposals by MSCAs or industry, 60 per year expected
      - ✓ **198 dossiers submitted**
      - ✓ **65 RAC Opinions finalised**
    - ✓ Monitored *via* Registry of Intentions

Risk management instruments: Authorisation and Restriction

- **Authorisation**
  - 'Substances of very high concern' (SVHCs): CMRs, PBT/vPvB or 'equivalent concern'
  - Identification (by Member States or by European Commission request to ECHA) onto the 'Candidate List'
  - (Some) transferred onto the 'Authorisation List' (Annex XIV)
  - Once on the Authorisation List, can only be marketed or used after 'sunset date' if authorised by the European Commission who decides based on an ECHA's Committees (**RAC & SEAC**) **Opinion**

- **Restriction** when unacceptable risks to humans or the environment have been identified
  - Member State Competent Authorities (or ECHA upon request from European Commission), submit dossiers proposing restrictions
  - European Commission Decision based on an ECHA's Committees (**RAC & SEAC**) **Opinion**
  - Annex XVII of REACH lists all restrictions

Relationship between Restrictions and Authorisation: scientific basis for decisions

Restriction

- The decision to restrict a substance or/and use shall take into account
  - Whether there is an unacceptable risk to human health and/or the environment
  - Appropriateness of the proposal to reduce the risk
  - The socio-economic impact of the proposed restriction

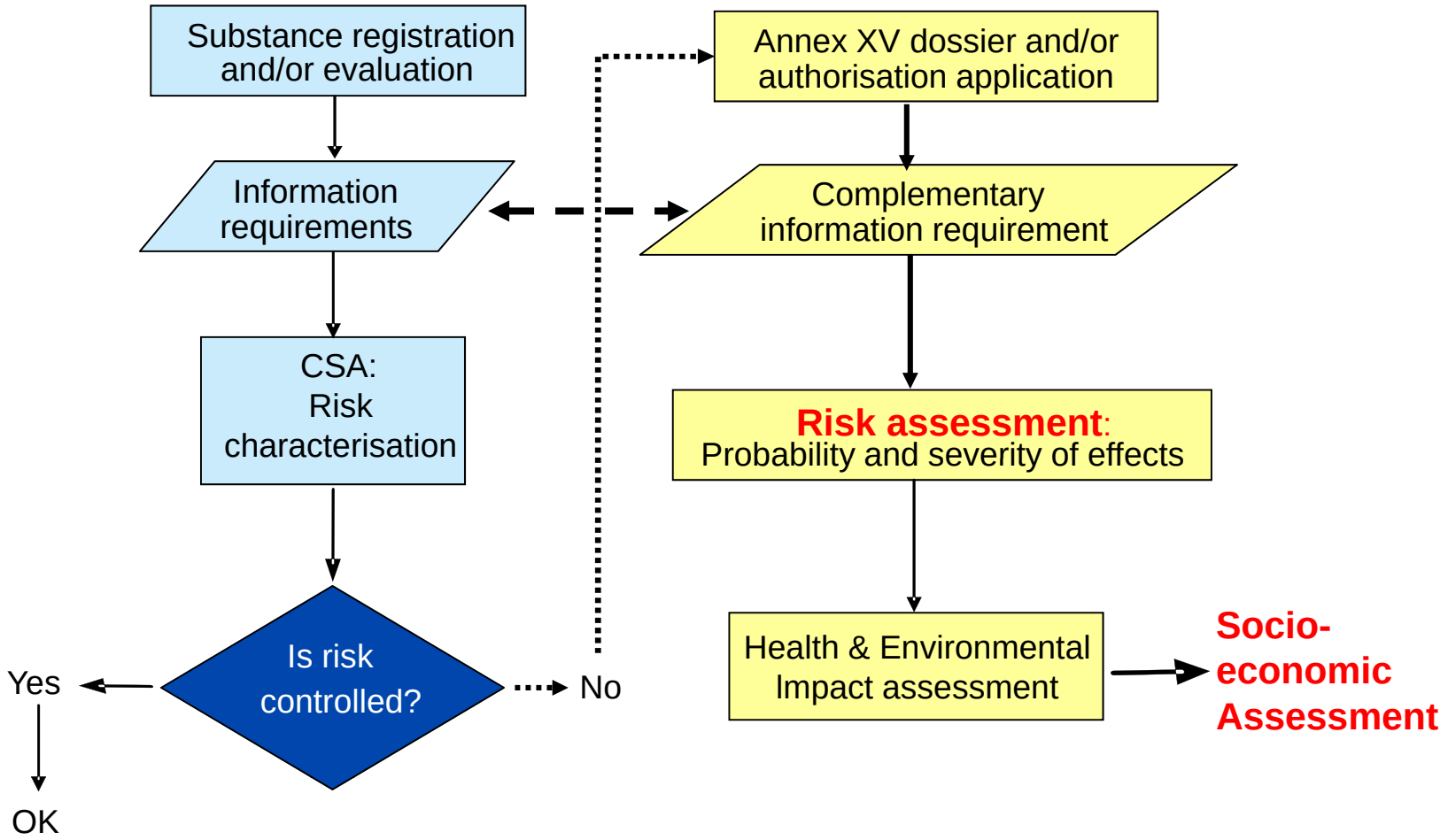
Authorisation

- Authorisations can be granted if
  - Risks to health and environment are adequately controlled

    or
  - No alternatives are available and socio-economic benefits outweigh the risks to health and environment

Risk assessment and socio-economic analysis is needed. REACH establishes two scientific committees, the Committee for Risk Assessment (**RAC**) and the Committee for Socio-economic Analysis (**SEAC**)

Links in the REACH processes



Chemical Safety Assessment

- Substances at >10 tonnes per year have Chemical Safety Report (CSR) to record the Chemical Safety Assessment (CSA).
- Hazard assessment, exposure assessment if hazardous and/or if PBT/vPvB.
- Determine 'Derived No Effect Level' (DNELs) for human populations, i.e. level below which adverse effects should not occur, based on toxicity data set using 'assessment factors'.
- PNECs for the environmental compartments.
- 'Exposure scenario' (ES) key output of the CSA process, i.e. a description of manufactured/used as 'Operational Conditions' (OCs) linked to 'Risk Management Measures' (RMMs).
- Exposure assessments are estimated using the ESs, for subsequent risk characterisation.
- CSR summarised as an extended Safety Data Sheet (SDS), i.e. essential element of supply chain communication to Downstream Users.
- Guidance & CHESAR tool.
- ECHA-Stakeholder Exchange Network on ESs.

From risk assessment to impact assessment

- Epidemiological or human experimental data if available
- Toxicological studies
  - Basis for deriving no-effect or minimal-effect levels (DNEL/DMEL)
  - Used together with exposure estimates to compute risk characterisation ratios (RCR = Exp / DNEL)
  - RCR>1 indicates concern, but does not give insight into the likelihood and magnitude of impacts

Comparison between CSA and IA

	Chemical safety assessment	Impact assessment
Exposure	"Representative individual", often not specifically identified location	Populations, space and geographic location relevant
Toxicity	Usually based on No-Observed-Adverse-Effect-Levels (NOAELs)	Probability of an effect
Risk charac-terisation	Usually based on the comparison of exposure with defined thresholds	Probabilistic estimate of the risk, i.e. on the dose-response function
Outcome	Assessment if risk is controlled, usually not aimed at identifying exact targets.	Number of people, species, amount of ecosystems affected.

→ECHA webpage– organised according to ECHA's missions and services

WWW.ECHA.EUROPA.EU

Thank you

Pilar.RODRIGUEZIGLESIAS@echa.europa.eu