European Commission

REACH

The European Union proposal for chemicals management

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Delegation of the European Commission to the US

WHY do we need REACH?

Problems

Current chemicals management system is inefficient

- Difficult to identify risks – difficult to address risks:
  - Lack of information about most substances on the market
  - Burden of proof on public authorities
  - No efficient instrument to deal with problematic substances
- Lack of incentives for innovation
- Lack of confidence in chemicals

Burden of the Past

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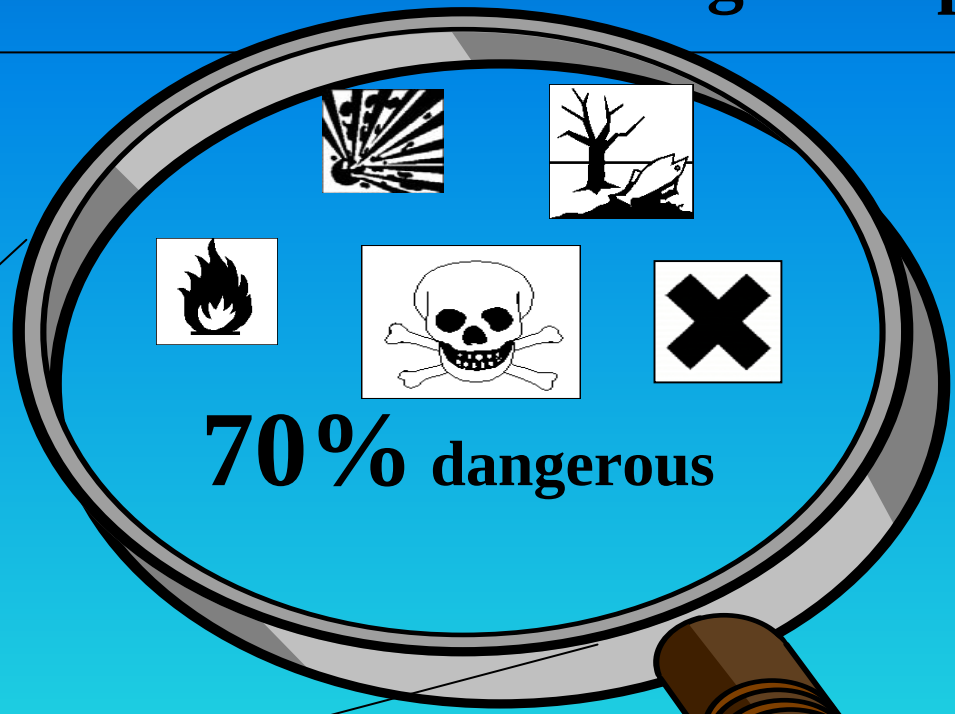
New substances - Knowledge of dangerous properties



70% dangerous

3.500 new substances

100% tested

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Existing substances - Knowledge of dangerous properties

30,000
existing substances

2600 HPV substances *:
3 % … tested
11 % … Base Set
15 % … almost Base Set
15 % … no data
56 % … often data for acute toxicity

*… Evaluation by the ECB.
~~HPV = high production volume(>= 1000 tons/year/~~ manufacturer). These substances make out over 95% of the chemicals on the market.

Solution: A New EU Chemicals Policy

Objectives

- Sustainable Development
  - Protection of human health and the environment
  - Maintain/enhance innovation/competitiveness
  - Maintain the Internal Market
  - Increased transparency and consumer awareness
  - Integration with international efforts
  - Promotion of non-animal testing
  - Conformity to WTO obligations

R E A C H

Substitution and precaution underpin system

What is REACH?

High level of health and environmental protection with the goal of achieving sustainable development.

- Single coherent system for new (non phase-in) and existing (phase–in) chemicals
- Elements:
  - Registration of substances ≥ 1 tonne/yr (staggered deadlines)
  - More information and communication through the supply chain
  - Evaluation of some substances
  - Authorisation only for substances of very high concern
  - Restrictions - the safety net
  - Agency to manage system
- Focus on priorities:
  - high volumes (early deadline)
  - greatest concern (CMRs early)

A Tiered Approach

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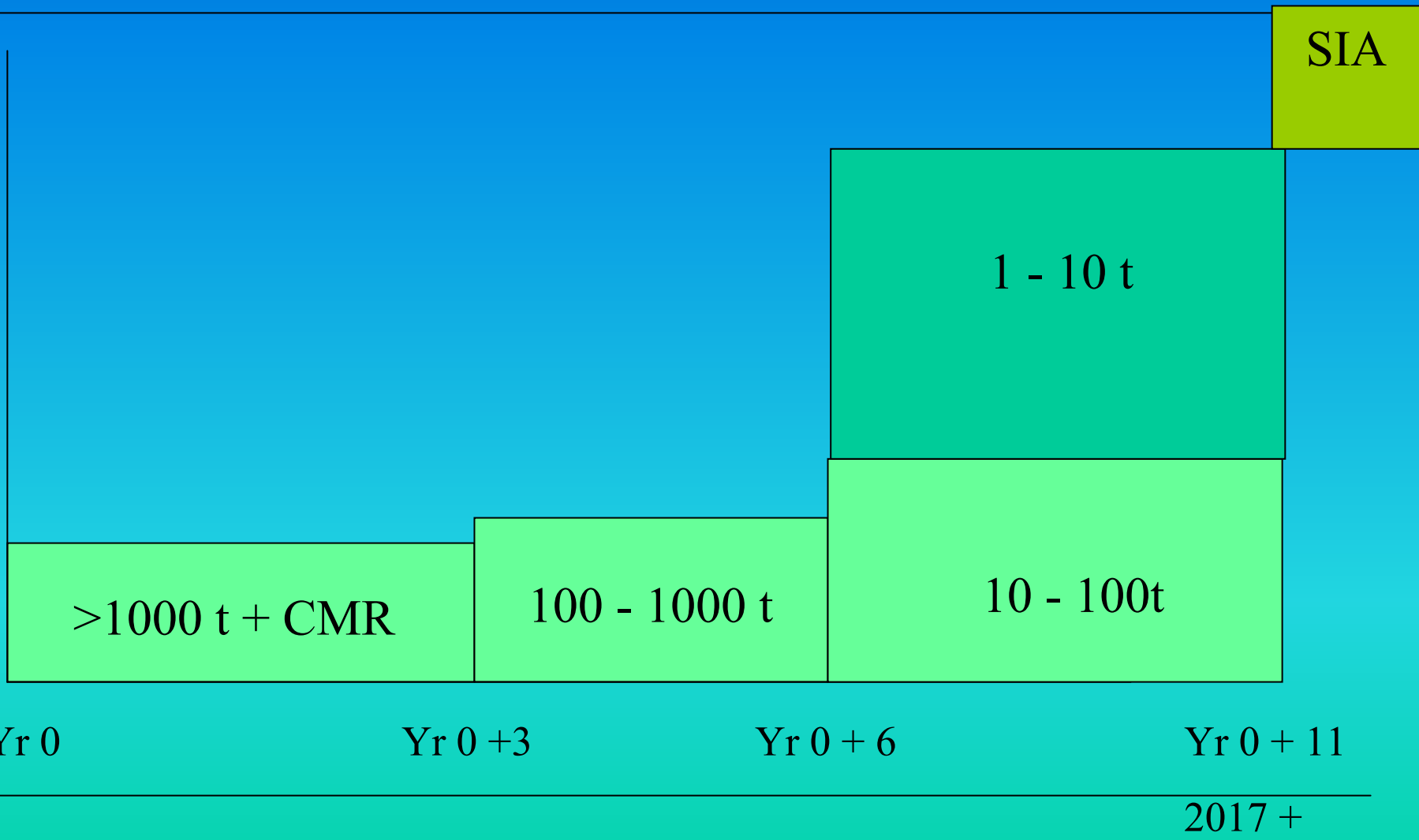
Registration: Deadlines



Generation of Information

Annex IX = F L E X I B I L I T Y

- (Q)SARs
- Use of category approaches
- Analogs, read across
- Available data (non-EU, GLP, non-GLP)
- Exposure based waiving (Annexes VII and VIII)
- Historical human data
- Data sharing (existing and new)

Testing (*in vitro*, *in vivo*) as a last resort

Substances in Articles

11 years and 3 months after entry into force (2017+)

- Meet the criteria for classification as dangerous
- > 1 t/yr per article type per M/I
- Not registered further up the supply chain

Intended to be released

General obligation to register

- Known to be released and
- Quantity released may adversely affect human health or the environment

Obligation to notify the Agency

Agency may require registration

Authorisation

Ensure risks from substances of very high concern are properly controlled ● Promote substitution.

- CMR, PBT, vPvB, 'serious and irreversible effects';
- Prioritised (progressively authorised as resources allow);
- Applicant to show:
  - adequate control of risks, or
  - social and economic benefits outweigh the risks
- Socio-economic authorisation - normally time-limited
  - substitution plan considered
- DU can use suppliers authorisation

Information through the supply chain

Improve risk management

- What:
  - Expanded MSDSs with exposure scenarios
  - Information on risk management, authorizations, restrictions, registration number etc.
  - Information up the supply chain on new hazards
- Result?
  - more information on risks
  - downstream users benefit
  - dialogue up/down the supply chain-encouraged/stimulated

Downstream Users (DU)

- Manufacturer/importer to cover all uses identified by downstream users.
- DU benefit from choice of:
  - supplier carrying out assessment, or
  - for confidentiality reasons doing own assessment.
- If using suppliers info,DU just have to:
  - implement supplier's RRM for identified uses
- If other use, DU will have to:
  - perform assessments only for 'unidentified uses' (using supplier hazard information)
  - inform Agency of 'unidentified uses' ≥ 1 tonne

Costs

- Impact Assessment:
  - Direct costs: €2 billion (range €1.6 - 2.9 billion).

Less than 0.1 % of annual turnover over 11 years

  - Total costs (inc to downstream users): €2.8 – 5.2 billion
  - Substance loss: 1-2% (to be further investigated)
- 60 % of direct costs from testing
  - An indication of the amount of information industry has about its chemicals?

The knowledge gap REACH is designed to fill

Benefits

- Simplification
- Level playing-field for new and existing substances
- Improved innovation (higher demand for safer substances)
  - higher registration thresholds
  - more R&D flexibility
- Health:
  - workers and public
  - difficult to assess but estimated €50 billion (over 30 yrs).
- Environmental benefits hard to express in cash terms (further work ongoing)

Conclusion: significant benefits

Key issues

1. **Prioritisation (Registration)**
   - Right balance
   - Short/long term impacts
2. **1-10 tonnes: Testing requirements**
3. **OSOR**
   - Mandatory sharing of all data
   - Workability of agreement
4. **Agency**
   - Stronger role in evaluation
5. **Substances in Articles**
   - Balance between protection, workability and WTO concerns

Commission's Interim Strategy

- Commission's practical preparations
  - Before REACH coming into force: Jan 2004 – early 2006
  - In co-operation with industry and MS
- Refocus Current Activities
- REACH Implementation Projects (RIPs):
  - RIP 1: Process descriptions (available on ENV website)
  - RIP 2: Development of IT systems (REACH-IT)
  - RIP 3/4: Guidance Documents (industry/authorities)
  - RIP 5/6: Preparation for start-up of Agency
  - RIP 7: Commission preparations
- Strategic partnerships

Progress in co-decision: Timing

Nov 2003: Proposal submitted to Parliament and Council

Decision making in EP and Council: 2004-2006

- **Political agreement between Member States: end of 2005?**
- **Parliament 1st reading: November 16, 2005**

REACH in force: 2007?

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Chemical Management Services and REACH

- REACH is based on information, documentation, evaluation and minimisation of hazards and risks and will trigger:
  - Joint responsibilities for producer and user
  - Precious basic material for the know-how development in service-oriented strategies such as data collection, “leasing” of chemicals, tracking MSD sheets, maintaining inventories of all kinds, tracking chemical use
  - Strategic partnerships

Information

EUROPA

Thank you!

http://europa.eu.int/comm/environment/chemicals/index.htm

http://europa.eu.int/comm/enterprise/chemicals/index.htm