European Commission, DG Environment
Unit C.3: Chemicals

REACH

Goals of REACH

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Structure

- Goals of REACH and how they are delivered
  - Introduction to proposal
  - Costs and benefits
- Progress in co-decision
- The Commissions interim strategy for the practical preparations for REACH.

White paper objectives

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

Substitution and precaution underpin system

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
- Low consumer confidence

Burden of the Past

GOALS of REACH

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

- Improving health and safety of workers and the general public.
- Environmental protection – avoiding chemical contamination of air, water, soil and damage to biodiversity
- Maintaining a competitive/innovative chemicals industry

Introduction to REACH

One System

- Single, coherent system for new (non phase-in) and existing (phase–in) chemicals
- Elements:
  - Registration of substances ≥ 1 tonne/yr (staggered deadlines)
  - Evaluation of some substances by Member States
  - 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

Registrant collects information to manage risks

- Scope
  - substances produced/imported ≥ 1 tonne/year
  - Isolated intermediates: reduced requirements.
  - Exemptions e.g. PPORD, polymers
- Tasks of the registrant (manufacturer/importer only):
  - obtain adequate information
  - produce CSR for substances > 10 tonnes/year (prove safety of uses)
  - send information to Agency by deadline (and to clients)
- Consortia encouraged

No formal acceptance - industry retain responsibility

Chemical Safety Assessment

- Scope: substances subject to registration > 10 tonnes/ per year
- Documented in Chemical Safety Report (registered)
- Process description in Annex I:
  - Physicochemical, human health and environmental hazard assessment
  - PBT and vPvB assessment

  and if necessary:
  - Exposure assessment and exposure scenario generation
  - Risk characterisation (demonstrate adequate control for HH and ENV)
- Elements communicated in SDS down the supply chain.

Protecting Health and the Environment

Product and Process Orientated R&D

- Wide definition
- 5-year exemption from Registration – notification required
- 4 weeks delay before manufacture or import
- Agency may impose conditions
- Extension by up to 5 years/up to 10 years for medicines
- Decisions by Agency
  - MS Competent Authorities comment on draft decisions
- All information treated as confidential

Enhancing innovation

Data sharing

Avoidance of unnecessary animal testing + save costs

- Information > 10 years – freely available
- At registration – registrants indicate if share non-animal data
- Non-phase-in substances:
  - Agency enables contact with previous, or potential, registrants – share costs
  - Studies involving vertebrate animals not repeated
- Phase-in substances:
  - Potential registrants of substance: 'SIEF' (Substance Info Exchange Forum)
  - Share data (inc new tests) and costs;
  - Sharing mandatory (vertebrate animals)

Evaluation:

Provide confidence that industry is meeting obligations

Prevent unnecessary testing

Dossier evaluation

Check test proposals

Compliance

Substance evaluation

Examine any information on a substance

Output:

- Further information decisions.
- CA to use information – authorisation or restrictions.
- CA to inform COM, Agency, other MS of conclusions - whether/how to use info.

Authorisation

Ensure risks from substances of very high concern are properly controlled or that they are substituted.

- 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

Restrictions

Safety net

- Community wide concern
- MS or COM initiated (Annex XIV dossier)
- Agency Committees examine:
  - the risk, and
  - the socio-economic aspects involved
  - 3rd party comments
- Consumer use CMR substances - fast track possible.
- Commission - final decision through comitology
- Carry-over of existing restrictions (76/769/EEC)

European Chemicals Agency

- Day to day management of REACH
  - Technical, scientific and administrative aspects
- Responsibilities:
  - Registration - reject or require completion of registration
  - Evaluation - ensure a harmonised approach; take decisions.
  - Substances in articles - require registration
  - Authorisation/restrictions - facilitate process; suggest priorities.
  - Secretariat for Forum and Committees
  - Deal with appeals - registration, R&D, evaluation, confidentiality

Information through the supply chain

Improve risk management

- What:
  - Classified substances: expanded SDSs with information from Chemical Safety Reports (exposure scenarios)
  - Non-classified substances: available/relevant information to enable RMM to be identified and applied.
  - 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 CSR 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 CSR just have to:
  - implement supplier's RRM for identified uses
- If carrying own CSR will have to:
  - perform assessments only for 'unidentified uses' (using supplier hazard information)
  - inform Agency of 'unidentified uses' ≥ 1 tonne

SMEs: concerns taken into account

- Many SMEs are DUs
  - no registration - report information at most.
  - require their supplier to perform the safety assessment
- SME manufacturers and importers - likely to be in 1-10t range
- Will get shared data from large companies
- Supplier authorisation can be used by customers.
- SMEs benefit from the provisions to encourage innovation

INTERNATIONAL COMPETITIVENESS

- REACH also applies to non-EU producers and importers (otherwise major loophole)
  - Substances imported from outside EU: same requirements as for EU (Registration; etc.)
  - Articles imported from outside EU: reduced requirements: Registration of substances in articles only if
    - Substance in article >1 t/y (per importer per article type)
    - Substance is dangerous
    - Substance is intended to be released (eg. toner) or shown to be released
- WTO compatible

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

Conclusion: significant benefits

Costs

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

    Less than 0.1 % of yearly turnover over 11 years
  - Total costs (inc to downstream users): €2.8 - 3.6 billion
  - Substance loss: 1-2%
- Further assessment of specific cases with industry / NGOs /Unions /Consumers
- 60 % of direct costs from testing

The knowledge gap REACH is designed to fill

Follow-up of the Impact Assessment

Objectives

- Undertake targeted complementary work on key issues related to the impact of REACH on the chemical supply chain

Methodology

- Case study approach (factual evidence)
- Highlight critical points along the value chain*
- Adequate verification and validation process

Timeframe

- May-End 2004

** Comprehensive analysis of specific value chain*

Follow-up of the Impact Assessment

Process

- Setting up a Working Group
  (inclusive process with all stakeholders)
- Establish an High Level Group
  (making the link between the WG and the policy making process)

Scope

- Chemical supply chain (e.g. withdrawal of chemicals, business benefits)
- Innovation (e.g. flexibility and time to market)
- Accession Countries

Timing

Nov 2003: Proposal submitted to Parliament and Council

Decision making in EP and Council: 2004-2005

- **Regular meetings in Council Working Groups**
- **Parliament lead to environment committee**

REACH in force: early 2006?

Progress

- Ad-hoc Working Party on Chemicals established (November 2003)
- Under the IRL and NL Presidency, the Ad-hoc Working Party on Chemicals has met on 12 occasions; and has:
  - completed a ‘high level’ reading of the main ‘building blocks’ of the REACH proposal
  - examined in greater depth many of the issues of significant interest.
  - started examination of titles I to III and testing annexes

Preparation: Commission 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

Conclusion

- REACH will ensure:
  - High level of protection of HH and ENV
  - Improve innovation
  - Protect competitiveness
- Benefits outweigh the costs

Information

EUROPA

Thank you!

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

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