REACH

Ecopa -Workshop

Current status of REACH legislation and implementation

1 February 2006

Mark Blainey

DG Environment, European Commission

WHY do we need REACH?

Current chemicals management system is inefficient

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

Protection of health and the environment, including wildlife, balanced against protection of the welfare of laboratory animals*.

*White Paper objective

REACH - key elements

- Registration of substances ≥ 1 tonne/yr
- Improved information and communication in the supply chain
- Evaluation of some substances by Member States
- Authorisation only for substances of very high concern
- Restrictions - the safety net (Community wide action)
- Agency to efficiently manage system

Focus on priorities:

Substances with high volumes and of greatest concern register first.

Progress in co-decision

Parliament: First reading: 17 November 2005

Council: Political agreement by unanimity: 13 December 2005

- 2006 2nd reading in Parliament
  - conciliation?
- 2007 Entry into force
- 2008 Agency starts
- **2010 First Registration deadline**

After co-decision…

What will REACH look like?

Pre-registration (1)

- Commission proposal for data-sharing mostly retained
  - Mandatory sharing of vertebrate animals data
  - Non-phase-substances:
    - Potential registrant enquires at Agency
    - Agency puts in touch with previous registrants (if any)
    - Animal tests shall be shared
  - Phase-in substances:
    - Pre-registration of substances
    - All potential registrants of one substance: SIEF:
      - ➔Any data holder can submit information to SIEF
      - ➔Participants share data
      - ➔Decide who does new test
      - ➔Owners of data who don’t share: can’t proceed with Registration

Pre-registration (2): Phase-in substances

- When?
  - Council 12-18 months
  - EP: until 18 months (+ 6 months if DU sees substance not pre-registered)
- What?
  - Substance name, potential registrant details (or 3rd party representative), deadline for registration.
  - Council: similar substances (for read-across).
  - EP: uses intended to be supported.
- Agency publishes list of information on website

Pre-registration (3): OSOR

- Data sharing
  - Animal data always shared
  - Non animal data:
    - Council: on request
    - EP: Mandatory with justified opt outs (Agency considers justification on request):
      - ➔Costs are disproportionate;
      - ➔Data is not relevant;
      - ➔Information is commercially confidential

Registration (1)

- **100 tonnes + as Commission proposal except:**
  - clarification of exposure based waiving conditions 18 months after EIF
  - early registration of PBTs/vPvBs (R50/53) > 100 tonnes (3 years)
    - EP: also registration of R50/53 > 1 tonne (6 years)
- **10-100 tonnes as Commission proposal except:**
  - EP: Information from Annexes V (extended) and VI (as amended = COM but
    - reprotoxicity testing only if assessment of information shows required
    - specific waiving of mutagenicity tests allowed and clarification of waiving for the 28-day study)
  - Council: Information from Annexes V (extended) and VI (as amended = COM – 1 reprotoxicity test)

Registration (2)

- **1-10 tonnes**
  - Physicochemical properties of Annex V (+ available information).
  - New substances provide full Annex V (extended)
  - Screening by registrant:
    - likely CMR, PBT or vPvB, or
    - Dangerous for health and environment pus wide-spread exposure?
    - If screening criteria are met → full Annex V (extended)
  - Annex V (extended)
    - Council: COM plus acute toxicity (oral), biodegradation, aquatic plant study.
    - EP: COM plus acute toxicity (oral), biodegradation
  - EP: CSR for substances which are likely CMRs, PBTs or vPvBs / for all substances registered

Registration (3)

Information:

- Existing information is acceptable (if quality ok)
- Read across, (Q)SARs, *in vitro* tests acceptable if validated
- Some information requirements may be waived (not carried out):
  - Because testing can't be done on a substance
  - For some tests (mainly in Annexes VII and VIII) because of no/limited exposure
- <u>New testing as a last resort</u>

Registration (4): OSOR

- Joint data submission: mandatory with opt outs:
  - Disproportionate cost
  - Commercial secrets
  - Disagreement on selecting data
- Justifications can be considered at evaluation

Evaluation (1)

Provide confidence that industry is meeting obligations

Prevent unnecessary testing

Dossier evaluation

Check test proposals

Compliance

Substance evaluation

Examine any information on a substance on CRP

Output:

- Further information decisions
- Info to other parts of REACH/other legislation

Evaluation (2): Dossier Evaluation

- Examination of testing proposals:
  - Priority to substances with CMR, PBT or vPvB properties, or dangerous and widespread use.
  - Registrant(s), or rarely DU, required to:
    - Carry out the proposed test
    - Carry out a modified test
    - Carry out additional tests
    - Not carry out the test
  - Agency decides who carries out test if > 2 registrants

Evaluation (3): Dossier Evaluation

- Examination of testing proposals (deadline):
  - Non-phase-in: 180 days
  - Phase-in: depending on tonnage:
    - 1000+: 5 years (registration deadline 3 years)
    - 100-1000: 9 years (registration deadline 6 years)
    - 1-100: 15 years (registration deadline 11 years)
  - List of registration dossiers being evaluated available to MS

Evaluation (4): Dossier Evaluation

- Compliance check of:
  - Correct information submitted in the technical dossier
  - Adaptations of the standard information requirements
    - Waiving statements justified
    - Correct use of (Q)SARs/read across/existing information/grouping
  - The Chemical Safety Report, esp RMM, justified
  - Any explanations relating to the non-joint submission of data (OSOR) justified.
- 5% of dossiers selected per year.

Evaluation (5): Substance Evaluation

- Community Rolling Action Plan:
  - Agency develops risk-based criteria for substances
  - Agency compiles 3 year plan of substances to be evaluated
  - 1st plan within 4 years of EIF
  - Annual updates
- Substances on plan evaluated – deadline 12 months
- Further information requested
  - Test in Annexes V to VIII
  - Other justified test
- Substances only looked at again if change of circumstances/knowledge

Evaluation (6)

- COM proposal maintained in structure but **increased responsibilities for the Agency**
  - Parliament
    - Responsible for all evaluations (but will rely on MS nominated bodies)
    - Agency establishes draft Community rolling plan (CRP) for substance evaluation
  - Council
    - Responsible for dossier evaluation
    - Responsible for substance evaluations (but will rely on MS CA)
    - Agency establishes draft Community rolling plan (CRP) for substance evaluation

Authorisation (1)

Ensure risks from substances of very high concern are properly controlled and eventually substituted.

- Commission proposal mostly maintained:
  - Applies to substances of high concern:
    - CMR, PBT, vPvB
    - ‘equivalent concern substances with serious effects’;
  - Substances prioritised (progressively authorised as resources allow);
  - Authorisations granted by the Commission
  - DU can use suppliers authorisation

Authorisation (2)

- Criteria for granting authorisations:
  - Council:
    - Authorisation granted if adequate control
      - ➔Not available for PBT, vPvBs or CMRs/substances of equivalent concern if not possible to determine a threshold.
    - Still possible to grant authorisation if socio-economic benefits outweigh the costs
    - Analysis of substitutes in all cases.
  - EP:
    - No suitable alternatives (= mandatory substitution), AND
    - Socio-economic advantages outweigh the risks, AND
    - The risk is adequately controlled.

Authorisation (3)

- Public list of substances to be authorised (eventually):
  - Council
    - Candidate list: substances meeting criteria
    - Annex XIII (substances prioritised and picked for authorisation within set timeframe)
  - Parliament
    - Annex XIIIa (candidate list: substances meeting criteria)
    - Annex XIIIb (substances prioritised and picked for authorisation within set timeframe)

Commission's Interim Strategy

- Commission's practical preparations
  - Before REACH coming into force: Jan 2004 – 2006
  - In co-operation with industry and MS
- 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

RIP 3.3

- Develop guidance for industry on how they can fulfil the information requirements on intrinsic properties of substances.
  - Better insight on how to use alternatives to *in-vivo* data such as (Q)SARs, category approach, *in-vitro* data etc.
  - Scoping study completed (July 2005).
  - Report at: http://ecb.jrc.it/REACH/
- The Commission services are now planning for the next phase (development of the guidance) of the project.

Is the reference to alternative methods to be employed taken seriously?

- From the Commission, YES:
  - creation of ECVAM,
  - under REACH new test at a last resort,
  - a specific RIP on this issue,
  - QSAR team at the ECB that deeply involved in OECD activities of QSAR and other *in silico* methods,
  - DG RTD funding projects: e.g.: ACuteTox (9 M Euro)
  - Clearly included in FP6 and FP7
  - 3Rs Conference in Nov 2005 with a 3Rs Declaration, followed by a creation of an Industry-Commission partnership to further promote the 3Rs

Has it been reflected in the future Framework Programme?

- In FP6:
  - a topic on "Intelligent Testing Strategies" for chemicals" has been selected, with an indicative budget of €10 millions. Two proposals have been invited to submit a complete proposal.
- FP 7 will adopted by the end of 2006
  - Council agreement obtained on 28 November 2005
  - The development of alternative methods are explicitly indicated in the *Environment and health heading*:

> "integrated risk assessment methods for hazardous substances including alternatives to animal testing;".

Conclusions

- REACH is on the horizon and agreement is likely by the end of the year.
- Protection of health and the environment, including wildlife, is balanced against protection of the welfare of laboratory animals.
- Good correlation between Council and Parliament:
  - What for Second Reading?
    - Registration
    - Authorisation and substitution
  - Conciliation?
- REACH Implementation Projects being prepared, including one on testing that includes insight on how to use alternatives.
- Commission takes development of alternative methods seriously.

Information

Thank you!

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

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