REACH and the protection of consumers:
The view from the Commission

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Commission services and REACH

• Lead on proposal: DG Environment and DG Enterprise
• Lead on technical and scientific implementation: DG Joint Research Centre
• Other services (closely) involved, e.g.:
  – DG SANCO
  – DG EMPL
  – DG MARKT
  – DG TRADE
  – DG TAXUD
  – Legal Service
Role of the JRC

- (technical) Support during drafting of legislation and the negotiation process
- Development of guidance documents and IT-tools
- Provide support (incl. human resources) to setting-up the Agency in Helsinki
- Provide scientific support to the Agency once established
Contents

- Basics of REACH and improvements in consumer protection
- Data availability and information generation
- What is Risk Assessment in REACH?
- What is the Commission doing to prepare for REACH?
• Basics of REACH and improvements in consumer protection
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
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

Substitution and precaution underpin system
Registration: general

AIM:
- manufacturers and importers obtain information on their substances and
- use this knowledge to ensure responsible and well-informed management of the risks these substances may present

Registration Dossier = Documentation

- Technical Dossier: starting at 1 tonnes per year
- Chemical Safety Report: starting at 10 tonnes per year

No formal acceptance - industry retain responsibility
Registration: Substances in articles

Substance: Dangerous and " 1 tonne per M/I per yr (per article type)?

Intended release

Registration

Unintentional release (Quantity Hazardous to HH or Env)

Release: known by producer/importer? made known to producer/importer?

Notification

Agency may require Registration

NB 1: The producer/importer does not have to register or notify substances in articles that have already been registered for that use up the supply chain (i.e. as part of CSR)

NB 2: Article 6 enters into force 11 years and 3 months after REACH enters into force
Evaluation

Provide confidence that industry is meeting obligations
Prevent unnecessary testing

Dossier evaluation
Check test proposals

Substance evaluation
Examine any information on a substance

Compliance

Output:
• Further information decisions
• Info to other parts of REACH/other legislation
Ensure risks from substances of very high concern are properly controlled or that the substances 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
Restrictions

Safety net

- Community wide concern
- MS/COM initiated
  - CMR substances for consumers - fast track possible.
- Agency Committees examine:
  - the risks, and
  - the socio-economic aspects involved
- Commission - final decision through comitology
- Carry-over of existing restrictions (76/769/EEC)
Information through the supply chain

Improve risk management

• What:
  – Expanded SDSs with information from Chemical Safety Reports (exposure scenarios)
  – Information on authorisations, restrictions, registration number etc.
  – Obligation to provide information up the supply chain on new hazards

• Result?
  – more information on risks
  – downstream users benefit
  – dialogue up/down the supply chain-encouraged/stimulated
C and L Inventory

- **Inventory:**
  - contains C and L info for all marketed substances (no tonnage limit)
  - managed by Agency based on submissions from industry
  - deadline – 3 years

- **Industry needs to co-operate to resolve differences in C&L**

- **EU harmonisation:**
  - CMRs
  - respiratory sensitisers
Benefits

• Systematic collection and sharing of available information
• Systematic assessment of risks
• More harmonisation of C&L
• Communication of conditions for safe use through the supply chain
• Authorisation of the most hazardous substances
• Faster restrictions procedure as a safety net
2. Data availability and information generation
IUCLID data availability for HPV-substances

- ≥ Base-set: 14 % (of 2465 HPVs)
- < Base-set: 65 %
- No data: 21 %

Data availability for ~25 000 non-HPVs (1 –1000 tpa):

???

Probably less data available, ........but how much information is in the drawers?
Lessons Learned from existing legislation

New Chemicals:
- substantial and reliable data is generated as the basis for assessing and determining appropriate risk management measures for a substance;
- few chemicals need additional risk management measures imposed by ‘authorities’ intervention

Existing chemicals:
- encouraging industry to submit previously unknown data, thereby preventing unnecessary tests being performed
- risk management decisions based on Classification & Labelling, the results of Risk Assessment and/or the holistic approach to risk management measures can render requirements for further testing unnecessary.
Design of Registration under REACH

- Minimum information set needed in REACH to enable a risk assessment to be carried out;
- Additional information should be required using a “top down approach”;
- Industry should make the proposals of which additional information is needed;
- But..........
- Information needs to be adequate for C/L and Chemical Safety Assessment (no box-ticking)
REACH and the use of test animals

- Testing on vertebrate animals shall be undertaken only as a last resort (art. 23)
- Information may be generated by other means than tests, in particular through (Q)SARs and read-across (art 12)

→ Legislative text + guidance should limit use of animals and prevent box-ticking
Intelligent Testing Strategies (ITS)

(Q)SARs

Read Across

In-vitro

Endpoint information

Existing information

Exposure Scenarios (Annex VII/VIII)

? TESTING
3. What is Risk Assessment in REACH?
What is Risk Assessment in REACH?

• Industry: Tool used in REACH to determine which risk management measures are **sufficient** for protecting (wo)man and the environment.

• MSs: Tool used in REACH to indicate that the currently implemented risk management measures are **not sufficient** for protecting (wo)man and the environment.
Exposure Scenario (ES)

- An exposure scenario sets out, for a given use, how the substance can be used in a way that risks are adequately controlled by describing:
  - Conditions for use:
    - Process descriptions (incl. quantity used)
    - Operational conditions (incl. frequency and duration of specified operations)
    - Risk Management Measures (process and emission control, personal protective equipment, good hygiene, etc.)
  - Other relevant information
Core tools under REACH

- The Chemical Safety Assessment (CSA) is the tool used to **determine**
- The Chemicals Safety Report (CSR) is the tool used to **record/document**
- The Safety Data Sheet (SDS) is the tool used to **communicate**

Conditions for use (for sufficiently protecting human health and the environment):

- risk management measures
- operational conditions
Exposure scenarios

Classification and labelling

Hazard assessment

Risk characterisation

Are risks adequately controlled?

YES

NO

ESs with RMM and operational conditions to adequately control the risks, to be:
Documented in the Chemical Safety Report (CSR)
Communicated to users (to downstream users via an SDS annex)
Chemical life cycle

Must be covered in a Chemical Safety Assessment

Toluene
- Adhesives
- Paints
- Sealants
- Solvents

Downstream uses = requirements for information exchange

SDS
Identification of uses

Professional use - brush
Professional use - spray
Consumer use - indoor
Consumer use - outdoor

Disposal
4. What is the Commission doing to prepare for REACH?
REACH Implementation Projects (RIPs)

- RIP 1: REACH Process Description;
- RIP 2: REACH – IT;
- RIP 3: Technical Guidance and Tools for Industry;
- RIP 4: Technical Guidance and Tools for Authorities;
- RIP 5/6: Setting up the (Pre-)Agency
3.1: Preparing the registration dossier
3.2: Preparing the CSR
3.3: Information requirements
3.4: Guidance on data-sharing
3.5: Guidance for downstream users
3.6: Guidance on C&L under GHS
3.7: Guidance on applications for authorisation
3.8: Requirements for articles
3.9: Guidance on SEA
3.10: Guidance on checking substance ID
Guidance on preparing a chemical safety report (CSR) (RIP 3.2)

• Develop guidance for manufacturers, importers and down-stream users of chemicals on how they can:
  • carry out the chemical safety assessment (CSA)
  • how they could document the CSA in the CSR, including listing of the exposure scenarios
  • how they can communicate information using the safety data sheet according to REACH.
RIP 3.2-1A (Scoping study)

- Overall workflow – CSA, CSR, SDS
- Focussed on further development of the exposure scenario (ES) concept – framework and examples
- How to incorporate ESs into SDSs?
- Targeting the chemical safety assessment
- Options for software development
- Tools and methodologies for SMEs – e.g. simpler but more conservative approaches
Information requirements (RIP 3.3)

- **Objective**
  - Guidance for industry on how they can fulfil the information requirements on intrinsic properties (Annex IV to IX)

- **Work will start with a scoping study developing the framework for ‘Intelligent Testing Strategies’**

- **Keywords**
  - Existing information, QSAR, in-vitro, read-across, exposure based waiving

- **Consider how to help SMEs in their decision-making**
RIP 3.8 on fulfilling article requirements

Further guidance on REACH Article 6:

- Evaluation of current experiences
- Operationalisation of terms (e.g. ‘article type’, ‘intended to be released’, ‘likely to be released’)
- Guidance for producers and importers of articles on when and how to notify and register
- Exemplification
Conclusions

• Consumer use of substances on their own, in preparations and in articles should be part of the M/I’s Chemical Safety Assessment and Report

• After EiF of REACH article 6 (11 years and 3 months) substances in articles not already tackled will be registered or notified (‘closing the gap’)

• REACH will substantially improve the knowledge on substances giving a better basis for the assessment of the risks from consumer use of substances

Challenges:
• Identification of substances in consumer products
• Development of ESs for consumer use
  – How are consumer products used?
  – Which RMMs can be assumed to be applied?
  – How to best communicate to consumers?
Further information on RlPs
http://ecb.jrc.it/REACH/

A proposal on a new EU regulatory framework for Registration, Evaluation and Authorisation of Chemicals (REACH) was adopted 29 October 2003. REACH aims to improve the protection of human health and the environment while maintaining the competitiveness and enhancing the innovative capability of the EU chemicals industry. ECB has the responsibility of developing methodologies, tools and technical guidance needed for REACH through a number of REACH Implementation Projects (RIPs). This is managed under Action no 1313 - Support to future chemicals legislation (REACH) or in short REACH Support.

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Overview

On 27 February 2001 the Commission issued a White Paper on a Strategy for a future Chemicals Policy. This has subsequently been developed and extensively discussed with major stakeholders, resulting in the release on 29th Oct 2003 of the Commission's proposal (REACH).

Under REACH enterprises that manufacture or import more than one tonne of a chemical substance per year would be required to register it in a central database. REACH would furthermore give greater responsibility to industry to manage the risks from chemicals and to provide users in the supply chain with safety information on the substances.

The proposal is now being considered by the European Parliament and the Council of the EU for adoption under the so-called co-decision procedure.