Introducing REACH

The New Chemicals Legislation for Europe

JMoE Symposium on REACH
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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 and the chemicals industry.

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WHAT is REACH?

- Regulation on the **R**egistration, **E**valuation and the **A**uthorisation of **CH**emicals
- Scope:

  manufacture, import, placing on market and use of substances (on their own, in preparations or in articles)
- Goals:
  - 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

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Key elements of REACH

- **R**egistration of substances ≥ 1 tonne/yr
- **E**valuation of some substances
- **A**uthorisation 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 those of greatest concern!

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Adopting REACH

- Proposal by the Commission: October 2003
- Adopted by the European Parliament and the Council
  - Fist reading by the European Parliament: November 2005
  - Common Position by the Council: June 2006
  - Final agreement reached: November 2006
  - Parliament adopts agreement (+529/-98/o24): 13 December
  - Council adopts agreement (by unanimity): 18 December
- REACH Regulation published in the OJ: 30 December
- Entry into force: 1 June 2007

After adoption…

How does REACH look like?

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REACH – Key elements

- **Registration** of substances ≥ 1 tonne/yr
- Increased information and communication throughout the supply chain
- **Evaluation** of some substances
- **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 those of greatest concern!

Registration

AIM: Ensure industry adequately manages risks from substances

- **What?**
  - Tonnage based
  - Registration deadlines: 3½-6-11 years
  - Limited information for intermediates and exemption for polymers
  - Limited information for research and development (PPORD)
  - Substances in Articles.
- **How?**
  - Manufacturer/importer obtains or generates adequate information
  - Electronic dossier submitted to Agency
  - Certain non-confidential information to central (largely public) database.

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Registration Requirements (1)

- Elements of a registration dossier:
  - 1 tonne and above: Intrinsic properties
  - 10 tonnes and above: Chemical Safety Report (CSR)
- Tiered testing:
  - 1-10 tonnes: Available information + Phys-chem properties in Annex VII (full Annex VII for prioritised substances)
  - 10-100 tonnes: Annexes VII and VIII.
  - 100-1000 tonnes: Annexes VII and VIII; testing proposals for information in Annex IX
  - ≥ 1000 tonnes: Annexes VII and VIII; testing proposals for information in Annex IX and X

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Registration Requirements (2)

	Health	Environment
1-10t prioritised	❑ *In vitro* skin and eye irritation ❑ Skin sensitiation ❑ *In vitro* mutagenicity ❑ Acute toxicity (one route)	❑ Acute aquatic toxicity – Daphnia ❑ Biodegradation – biodegradability and hydrolysis ❑ Acute aquatic toxicity – Algae
10-100t	❑ *In vivo* skin and eye irritation ❑ Further *in vitro* mutagenicity ❑ Sub acute toxicity (28 days) ❑ Reproductive toxicity screen	❑ Acute aquatic toxicity – Fish ❑ Activated sludge ❑ Adsorption/desorption screening
100-1000t	❑ Further mutagenicity tests ❑ Sub-chronic toxicity (90-days) ❑ Further reproductive toxicity tests	❑ Long term aquatic toxicity daphnia and fish ❑ Further degradation and fate/behaviour studies ❑ Short term effects on terrestrial organisms
>1000t	❑ Further mutagenicity tests ❑ Carcinogenicity ❑ Chronic toxicity ❑ Further reproductive toxicity tests	❑ Further degradation and fate/behaviour studies ❑ Long term effects on terrestrial organisms

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Registration – OSOR

Joint information	Hazard information and testing proposals Classification and labelling
Individual information	Company specific information Information to keep confidential
Choice	CSR Guidance on safe use Quality assessed

- ❑ Joint data submission: mandatory with opt outs:
  - ➢ Disproportionate cost
  - ➢ Commercial secrets
  - ➢ Disagreement on selecting data

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Registration: Animal Testing

- Data-sharing obligation avoids many tests
- New testing is only the last resort:
  - Existing information is acceptable (if quality ok)
  - Read across, (Q)SARs, *in vitro* tests acceptable if validated
  - Some information requirements may be waived:
    - Because testing cannot be done on a substance
    - For some tests in some volume bands because of no/limited exposure

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Registration – Substances in Articles

- Registration of substances intentionally released
  - Substance present above 1 tonne
  - Agency may require registration for substances which are not intentionally released from an article but present a risk.
- Notification of substances of very high concern if
  - SVHC present above 1 tonne
  - SVHC present above a concentration limit of 0,1%
  - Exposure of the public or the environment during the full life cycle cannot be excluded
  - Applies 6 months after substance is listed on authorisation candidate list.

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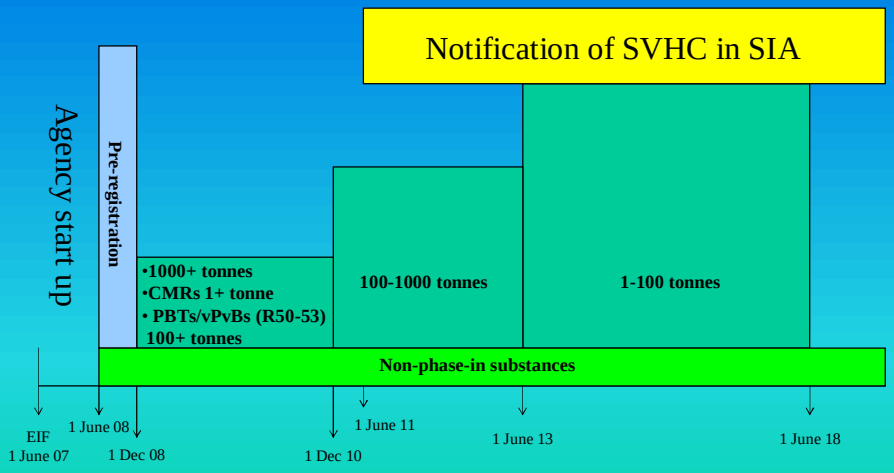
Registration Timeline



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Availability of Information

- Published on web, free of charge:
  - Information on substance identity,
  - classification,
  - physicochemical data,
  - results of toxicological and ecotoxicological studies,
  - DNELs, PNECs,
  - guidance on safe use,
  - analytical methods.
- Published on web, free of charge, unless companies justify otherwise:
  - Information on tonnage bands,
  - impurities,
  - information in the SDS (unless above),
  - study summaries/robust study summaries,
  - IUPAC name / trade name (for new dangerous substances up to 6 years).

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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'

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Information through the supply chain

- What?
  - Expanded SDSs – info from Chemical Safety Reports
    - Exposure scenarios as Annex
  - Information on authorisations, restrictions, registration number, info for risk management, etc.
  - Information on SIA (>0.1%w/w)
  - Information up the supply chain on new hazards and if received info is challenged.
- Result?
  - more information on risks
  - downstream users brought into the system
  - dialogue up/down the supply chain encouraged/stimulated

Encourage communication → Improve risk management

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Evaluation

Provide confidence that industry is meeting obligations
Prevent unnecessary testing

Dossier evaluation: Agency

Substance evaluation: Agency (MS)

Check test proposals

Compliance

Examine any information on a substance on CRP

Output:

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

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Authorisation

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

- Substances of very high concern:
  - Carcinogenic, mutagenic, reprotoxic (CMR)
  - Persistent, bioaccumulative and toxic (PBT)
  - Very persistent and very bioaccumulative (vPvB)
  - Substances of "equivalent concern for which there is scientific evidence of probable serious effects"

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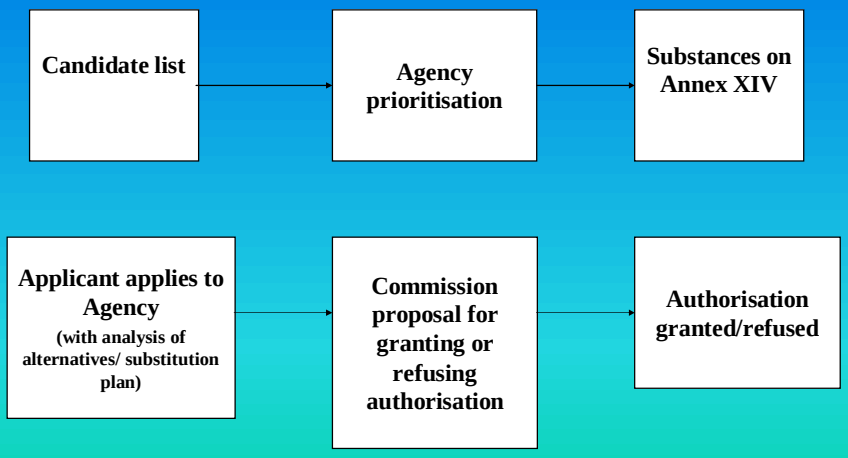
Authorisation - Overview



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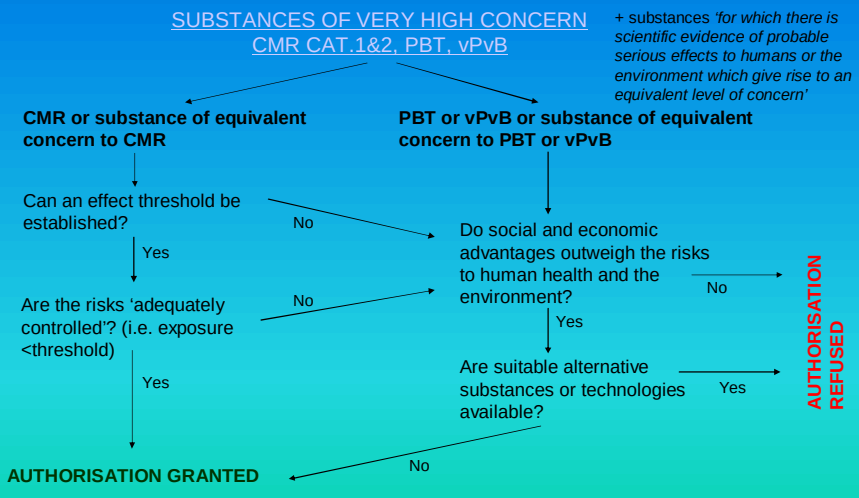
Authorisation Chart



Restrictions

AIM: act as safety net

- Community wide concern
- MS/COM initiated
  - Fast track possible e.g. CMR substances for consumers.
- Agency Committees examine:
  - The risk, and
  - The socio-economic aspects involved.
- Commission - final decision through comitology
- Carry-over of existing restrictions (76/769/EEC).

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

What next?

REACH Implementation

- End 2006 – Publication in the OJ
- June 2007 – Entry into force of REACH
  – Setting up the Agency in Helsinki
- June 2008 – Agency operational
- June 2009 – First substances prioritised for **authorisation**
- June 2010 – 'New' **restrictions**
- End 2010 – First **registration** deadline for ≥1000t &CMR
- End 2018 – Last registration deadline for ≥ 1t

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The Interim Strategy

4 basic work elements:

- **Re-focus Current Activities** → Aligning Dir. 67/548 and Reg. 793/93 with REACH
- **Preparing for REACH** → Developing Guidance Documents and Software Tools for efficient, transparent and consistent implementation
- **Strategic Partnerships** → "Working together, preparing for REACH"
- **Setting up the Agency** → Finland: Practical aspects; COM: Organisation

The Interim Strategy prepares ALL stakeholders for a Sustainable REACH Implementation

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The RIPs

- 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.

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Guidance for Industry & Authorities

- RIP 3/4:
  - Preparing a Chemical Safety Report *
  - Information Requirements *
  - Data-sharing (Pre-registration)
  - Downstream user Requirements*
  - Carrying out a Socio-Economic Analysis*
  - Preparing an Application Dossier for Authorisation
  - C&L under GHS
  - Preparing the Technical Dossier for Registration
  - Priority Setting for Evaluation
  - Dossier Evaluation
  - Substance Evaluation
  - Inclusion of Substances into the list of substances subject to Authorisation.

* Definitive document

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Stakeholder Expert Groups

- Discuss the project implementation, including work plan, deliverables and timing
- Discuss progress and advise on consequent adjustments needed to the work plan
- Provide comments on draft guidance documents
- Where relevant, and a mandate has been given by the Commission, carry out parts of the RIP work.

SEG Representation

- Approximately 200 experts follow the process!
- 19 MS or accession countries
- Industry organisations:
  - CEFIC, CEPE, CEPI, CONCAWE, DUCC, ESIA, Euratex, Reach Alliance, EuPC, BLIC, EDANA, Eurocommerce, AISE, ASD, FECC, UNICE, ESBA, CIA, EPIA.
- NGO's:
  - ETUC, FoE, WWF, ECEAE, EEB, Greenpeace.
- Others:
  - OECD secretariat, Health Canada, Japan Business Council in Europe.

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Example: Exposure Scenarios RIP 3.2

- Exposure Scenarios represent a new element of "risk assessment" and is central to REACH implementation;
- Industry, in particular sector / branch organisations should provide support by gathering best practice Risk Management Measures and developing generic but sector-specific Exposure Scenarios

The 'Arona network': Main conclusions

- A manageable number of ES is needed to cover standard processes within an industrial sector
- Bottom-up approach is a way forward in developing ES
- Use standard descriptions of current practice within industrial sectors as a starting point

Report and presentations at:
http://ecb.jrc.it/REACH
→ documents →Arona network

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Preparation for non-EU manufacturers

- No obligations under REACH
- Obligations lie on the importers
- Non-EU manufacturers could choose to have an only representative

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Preparation for non-EU manufacturers: importers

- Make an inventory of substances to be exported
- Study obligations of your EU importer
  - REACH registration requirements
  - Guidance developed: http://ecb.jrc.it/REACH/
- Actively communicate with your EU clients to see how their needs can be met and
  - Provide adequate information on the substances
  - Develop and provide exposure scenarios
- Plan for the future
  - Don't leave data generation and assessment too late

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Preparation for non-EU manufacturers: 'only' representative

- What are your uses and what are the identified uses?
- How can these best be expressed in (broad) exposure scenarios?
  - M/I: Specific scenarios cost more to prepare but may require less testing and less demanding risk management measures – attractive to DU
  - As a DU, do you wish to identify your use?
- M/I and DU - start talking to each other today!
- Use the flexibility in the Regulation
  - ES can be as broad as possible but need to be specific where necessary to communicate appropriate risk management measures

Conclusion

- REACH will be in force in a few months
- REACH will have benefits
- REACH opportunity to rebuild confidence in chemicals
- Start preparing now.

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EUROPA

Thank you!

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

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