



Introducing REACH

The New Chemicals Legislation for Europe

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European Commission - DG Environment

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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.



WHAT is REACH?

- Regulation on the **Registration, Evaluation and the Authorisation of **Chemicals****
- 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



Key elements of REACH

- Registration of substances ≥ 1 tonne/yr
- 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!



Adopting REACH

- Proposal by the Commission: October 2003
- Adopted by the European Parliament and the Council
 - First 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?



European Commission - DG Environment

REACH – Key elements

- Registration** of substances \geq 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.



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



Registration Requirements (2)

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



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



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

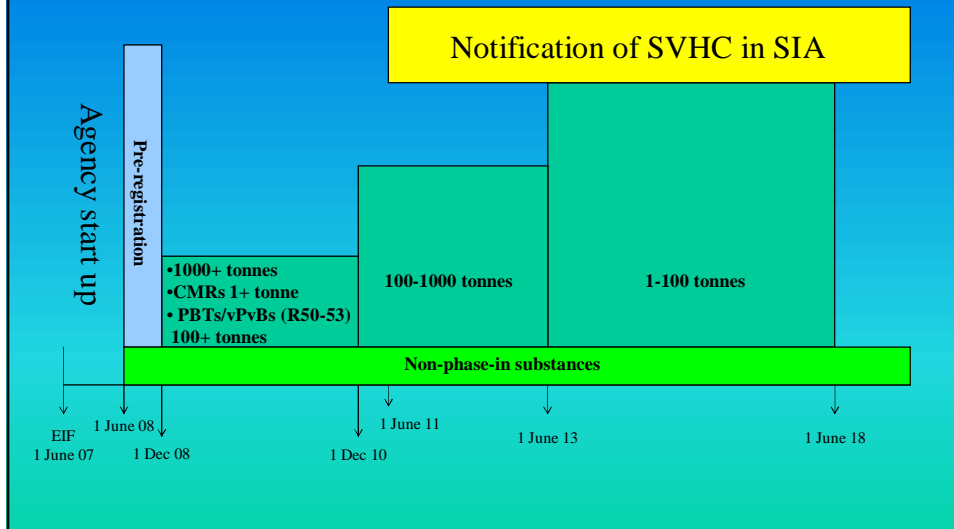


Registration – Substances in Articles

- ❑ 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.



Registration Timeline



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).



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'



Information through the supply chain

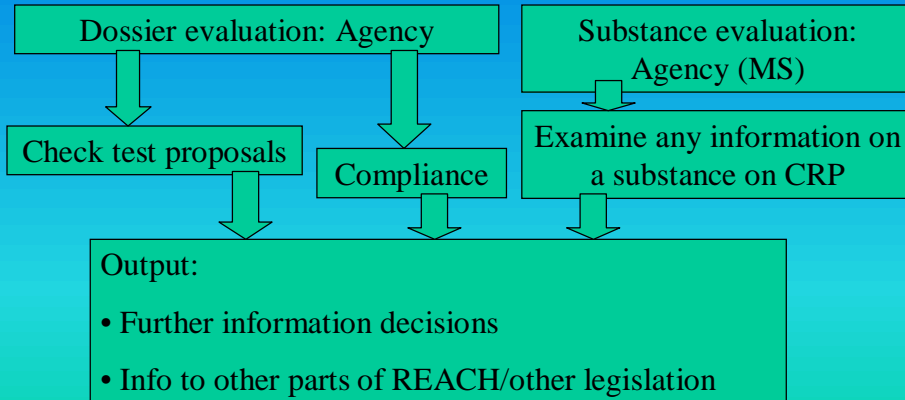
- What?
 - Expanded SDSs – info from Chemical Safety Reports
 - Exposure scenarios as Annex
 - Information on authorisations, restrictions, registration number, info for risk management, etc.
 - Information on SIA (>0.1% w/w)
 - Information up the supply chain on new hazards and if received info is challenged.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

Encourage communication → Improve risk management



Evaluation

Provide confidence that industry is meeting obligations
Prevent unnecessary testing



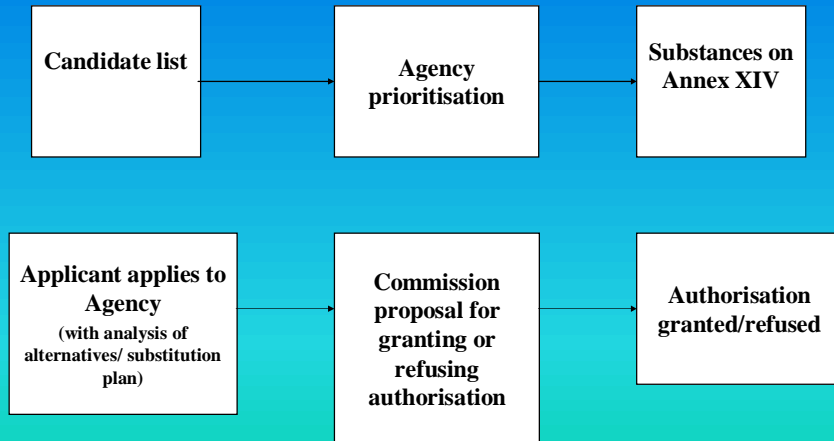
Authorisation

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

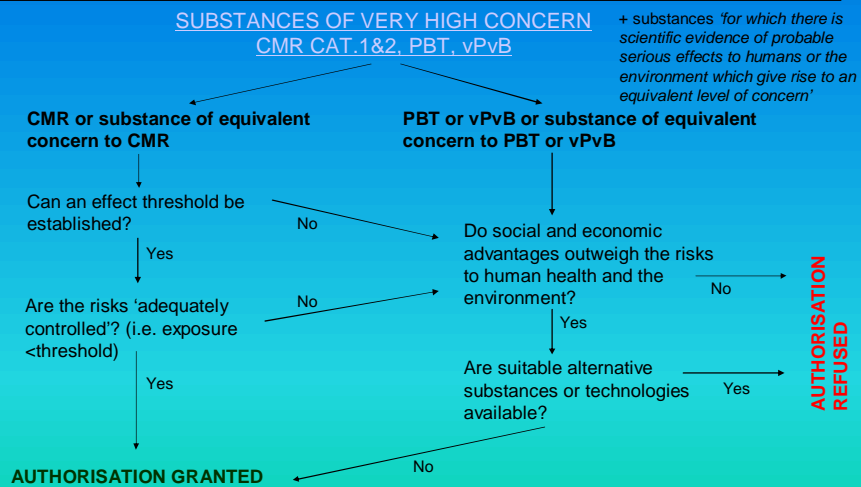
- ❑ Substances of very high concern:
 - Carcinogenic, mutagenic, reprotoxic (CMR)
 - Persistent, bioaccumulative and toxic (PBT)
 - Very persistent and very bioaccumulative (vPvB)
 - Substances of “equivalent concern for which there is scientific evidence of probable serious effects”



Authorisation - Overview



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).



European Chemicals Agency

- 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 $\geq 1000t$ & CMR
- End 2018 – Last registration deadline for $\geq 1t$



The Interim Strategy

4 basic work elements:

- Re-focus Current Activities
- Preparing for REACH
- Strategic Partnerships
- Setting up the Agency

Aligning Dir. 67/548 and Reg. 793/93 with REACH

Developing Guidance Documents and Software Tools for efficient, transparent and consistent implementation

“Working together, preparing for REACH”

Finland: Practical aspects
COM: Organisation

The Interim Strategy prepares ALL stakeholders for a Sustainable REACH Implementation



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.



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



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.



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



Preparation for non-EU manufacturers

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



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



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.



EUROPA

Thank you!

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

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