European Commission, DG Environment
Unit C.3: Chemicals

Legislating in the EU

Introducing REACH

EU Lobbying for Turkish Industry

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The role of the European Commission

- Legislative powers
  - Initiator of Community legislation
  - Development of Community's policies/legislative plan
  - Legislative power (on its own or delegate).
- Administrative responsibilities
- 'Executive' power of the European Union
  - Financial powers – Community budget
  - External relations.
- Judicial powers - watchdog of Community legislation.

The Legislative Process: Co-decision

- European Parliament and Council: co-legislators
- European Commission: right of initiative throughout the whole adoption process
  - It prepares and presents the legislative proposal
  - It's opinion determines voting requirements for the Council common position
  - Right to withdraw the proposal at any time.
- But… during the whole co-decision process the Commission
  - Provides technical assistance to EP and Council.

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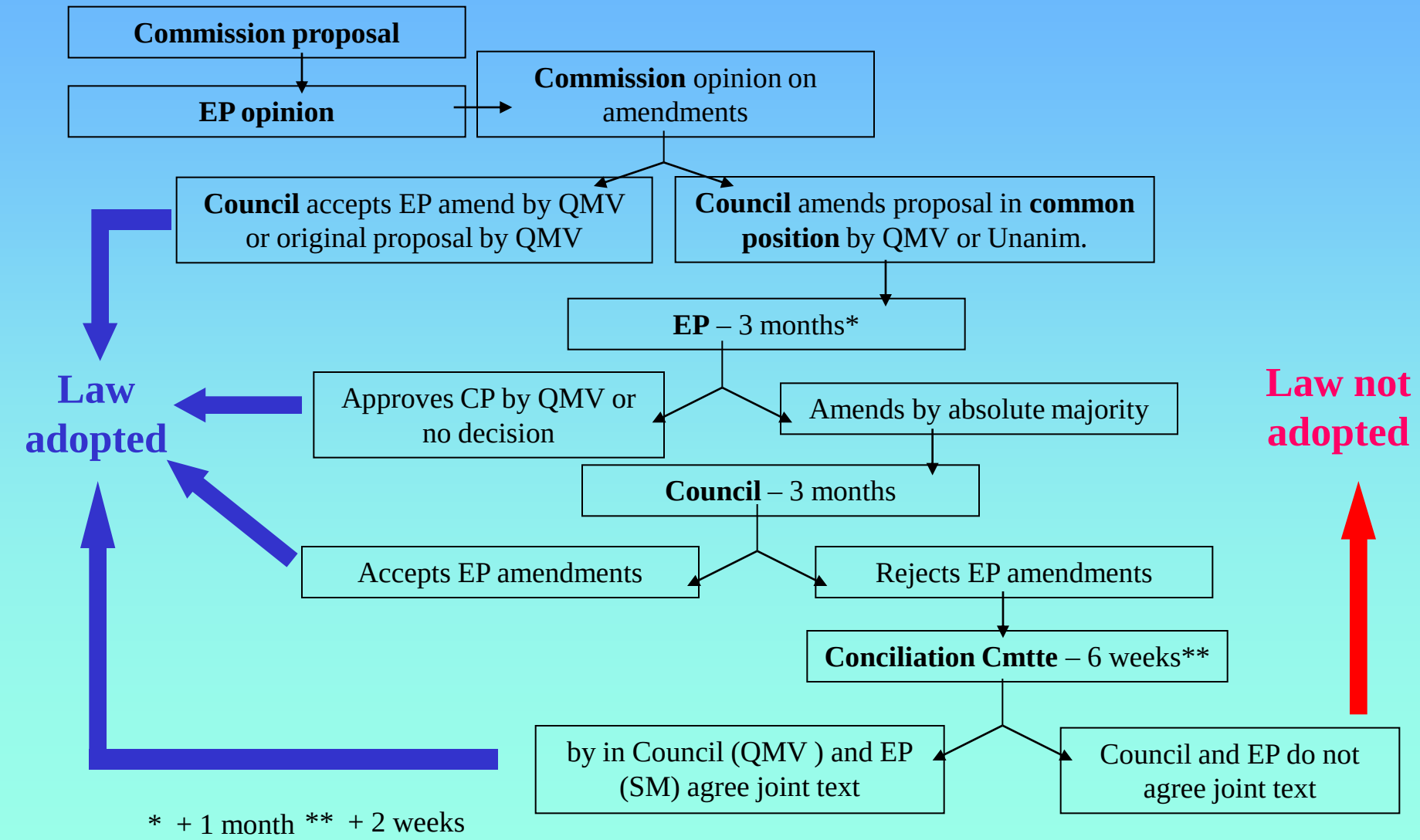
The Legislative Process: Co-decision



Initiating legislation: REACH

- Informal Council of Environment Ministers (Chester, 1998): trigger
- Commission White Paper (2001):
  - Concluded that the current regulatory framework for chemicals was inappropriate
  - That a reform was necessary to meet a series of core objectives.

Goals of REACH

- 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.

What is REACH?

- Proposal for a 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)
- Prioritises:
  - high volumes (early deadline)
  - greatest concern (CMRs early).

Elements of REACH

- Registration of all substances M/I ≥ 1 tonne/yr
- Evaluation of some substances by Member States
- Authorisation only for substances of very high concern
- Restrictions - the safety net
- Agency to manage system.

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Administering REACH

The **Interim Strategy** has 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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Information

Thank you!

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

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

Registration

AIM: Ensure industry adequately manages risks from substances

- **Method**:
  - M/I obtains/generates adequate information
  - Electronic dossier submitted to Agency
  - Certain non-confidential information to central (largely public) database.
- **Scope**
  - Substances M/I ≥ 1 tonne/year
  - Exemptions: other law, Annex II/III; polymers (review); PPORD
  - As registered: biocides, pesticides, notified substances.
- **Consortia encouraged**

Industry's responsibility

Registration: Safety Assessment

- In registration of all substances above 10 tonnes
- Documented in a Chemical Safety Report
  - Part of the registration dossier.
- Exemptions
  - Substances in preparations below certain concentration limits.
- Defined in Annex I
- Includes
  - Human health hazard assessment
  - Environmental hazard assessment
  - PBT and vPvB assessment.

Registration: Data Sharing

AIM: to avoid unnecessary animal testing + save costs

- **Information > 10 years** – freely available
- **Non-phase-in substances** (= new):
  - Already registered?
  - Agency enables contact - 50% cost sharing
  - Studies involving vertebrate animals not repeated
- **Phase-in substances** (= existing):
  - Potential registrants of same substance: 'SIEF'
  - Sharing mandatory (vertebrate animals), if participant refuses to share = sanctions
  - Equal sharing of costs.

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Registration: Consortia

Individual	Choice	« One for all »
Identity of M/I Identity of the substance Information on manufacture and use Statement whether information has been generated by testing on vertebrate animals	Guidance on safe use Chemical Safety Report	Summaries or robust study summaries of information derived from application of Annexes V bis IX Proposals for testing where required by application of Annexes V bis IX Classification and labelling

Registration: 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.

Information through the supply chain

- **What?**
  - Expanded SDSs – info from Chemical Safety Reports
  - Exposure scenarios as Annex
  - Information on authorisations, restrictions, registration number etc.
  - 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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Registration: Substances in articles

11 years and 3 months after entry into force (2017+)

- Meet the criteria for classification as dangerous
- > 1 t/yr per article type per M/I
- Not registered further up the supply chain

Intended to be released

General obligation to register

- Known to be released and
- Quantity released may adversely affect human health or the environment

Obligation to notify the Agency

Agency may require registration

Evaluation

- **Dossier evaluation**
  - CA from MS where registrant is based
  - Examination of testing proposals
  - Compliance check.
- **Substance evaluation**
  - MS prepare rolling plans
  - Mechanism to select one CA if several MS want to evaluate
  - Follow-up suspicion of risk: request more info.
- **Agency**
  - Sets priorities
  - Takes decisions if all MS agree (else comitology).

Member States' responsibility

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Evaluation

AIM: 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
- Info to other parts of REACH/other legislation

Authorisation

AIM: Ensure risks from substances of very high concern (SVHC) are properly controlled or that they are substituted.

- **SVHC** (CMR, PBT, vPvB, 'serious and irreversible effects')
- **Prioritised** (progressively authorised as resources allow)
  - each substance given individual deadline and use allowed until decision taken.
- **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.

Authorisation: Granting

- If the risks are adequately controlled

  (as documented in the CSR)
- If the socio-economic benefits outweigh the risks and if there are no suitable alternative substances or technologies.

European Commission's responsibility

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)
- POPs.

European Commission's responsibility

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.